UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

In re Bristol-Myers Squibb Company CVR Securities Litigation	No. 1:21-CV-08255-JMF **CONSOLIDATED SECOND AMENDED CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

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Lead Plaintiff Mangrove Partners Master Fund, Ltd. ("Mangrove" or "Lead Plaintiff"), along with Additional Named Plaintiffs Ehab Khalil, SM Merger/Arbitrage, L.P., SM Investors, L.P., and SM Investors II, L.P. (together, "Plaintiffs") bring this complaint against Bristol-Myers Squibb Company ("Bristol" "BMS" or the "Company"), Giovanni Caforio, Samit Hirawat, Vicki L. Sato, Peter J. Arduini, Robert Bertolini, Matthew W. Emmens, Michael Grobstein, Alan J. Lacy, Dinesh C. Paliwal, Theodore R. Samuels, Gerald L. Storch, Karen H. Vousden, Charles Bancroft and Karen M. Santiago (the "Individual Defendants") (together, "Defendants").

Plaintiffs bring this federal securities class action on behalf of all persons who purchased or otherwise acquired Bristol-Myers Squibb Contingent Value Rights ("CVRs") (NYSE: BMY-RT) from November 20, 2019 through December 31, 2020 (the "Class Period"), and who were damaged thereby (the "Class"). The claims asserted herein are based upon: materially false and misleading statements and omissions of material facts in the Registration Statement (filed on or about February 20, 2019, and defined to include accompanying prospectuses and documents therein) made in violation of Sections 11, 12(a)(2), and 15 of the Securities Act of 1933 ("Securities Act"); false and misleading statements and omissions of material fact made in the Joint Proxy (the relevant substance of which was also included in the Registration Statement, and which was filed on February 22, 2019) made in violation of Sections 14(a) and/or 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 14a-9 promulgated thereunder; and, for those persons who purchased CVRs on the open market, false and misleading statements and omissions of material fact, and devices, schemes and/or artifices to defraud all of which operated as a fraud and deceit, made throughout the Class Period in violation of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder.

Plaintiffs' allegations are based upon personal knowledge as to their own acts, and upon information and belief as to all other matters, such information and belief having been informed by the independent investigation of their undersigned counsel. This investigation included a review and analysis of: (i) public filings submitted by Celgene Corporation ("Celgene") and Bristol to the U.S. Securities and Exchange Commission (the "SEC"); (ii) research reports by securities and financial analysts concerning the merger (the "Merger") of Celgene and Bristol and concerning Bristol post-Merger; (iii) transcripts of Celgene and Bristol investor conference calls; (iv) publicly available presentations by Celgene and Bristol; (v) press releases, media reports, and social media postings; (vi) economic analyses of securities movement and pricing data; (vii) publicly available filings in other legal actions brought against Bristol; (viii) publicly available analyses and data concerning the U.S. Food and Drug Administration ("FDA") Biologic License Application ("BLA") approval process; (ix) interviews with former employees of Bristol, Celgene and their subcontractors and investors in the CVRs; (x) discussions with an expert in biologics and FDA approvals and inspections who previously worked for the FDA as a senior reviewer and investigator for its Center for Biologics Evaluation and Research, and who has performed pre-licensing inspections of numerous manufacturing facilities; (xi) regulatory materials exchanged between Bristol, Celgene, and Juno and the FDA, obtained via the Freedom of Information Act ("FOIA"); and (xii) other publicly available material and data identified herein. Counsel's investigation into the factual allegations contained herein is continuing, and many of the relevant facts are known only by Defendants or are exclusively within their custody or control. Plaintiffs believe substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

I. INTRODUCTION

1. This action arises from Defendants' intentional slow-rolling of the FDA approval

process for a blockbuster cancer therapy – JCAR017 a/k/a lisocabtagene maraleucel ("Liso-cel") – for the purpose of avoiding a $6.4 billion payment to CVR holders. A CVR is a security payable upon the occurrence of a specified future event (*e.g.*, upon obtaining regulatory approval for a drug candidate), often used by acquiring companies as partial merger consideration to the target company's shareholders. It was Bristol's idea to offer a CVR, and by Bristol's design, it was only required to pay CVR holders if all three different drug therapies at issue under the CVR—Liso-cel, Ide-cel and Ozanimod—were approved by the FDA by specified dates (the "Milestones"). A single therapy missing its Milestone by a single day was all Bristol needed to avoid a payment of $6.4 billion under the CVR Agreement.

2. The development of Liso-cel was so crucial to the treatment of diffuse large B-cell lymphoma—the most common subtype of Non-Hodgkin lymphoma cancer that kills approximately 20,000 Americans and 250,000 people worldwide each year—that the FDA designated it as a "Breakthrough Therapy," a "Regenerative Medicine Advanced Therapy," and a "Priority Review Therapy". These designations meant that Liso-cel would receive an expedited review process by a dedicated team of senior FDA personnel working with Celgene, and later Bristol, to ensure it would enter the market quickly and start saving and prolonging lives as soon as possible.

3. Despite this expedited review, Bristol successfully delayed the FDA's regulatory approval of Liso-cel for just enough time to avoid the $6.4 billion CVR payout to investors through a series of deliberate or reckless acts that it falsely passed off as unforeseeable mistakes or as events out of its control.

4. First, Bristol, one of the world's largest and most sophisticated pharmaceutical companies, submitted FDA filings that omitted volumes of basic information concerning Liso-cel

in contravention of industry standards and Bristol's own long-standing practices in a multitude of prior FDA filings. Bristol and the 10(b) Defendants knew that this and each subsequently defective submission would delay FDA review, inspection and approval of Liso-cel–and thus would make it more likely that Bristol would miss the Liso-cel Milestone and avoid paying CVR holders. According to an expert in biologics and FDA approvals and inspections who previously worked for the FDA as a senior reviewer and investigator for its Center for Biologics Evaluation and Research (the "FDA Biologics Expert"[1]), these omissions were not only glaringly obvious, particularly for a drug company of Bristol's sophistication and experience, but necessitated approval and oversight by Bristol senior executives.

5. Second, even though the delays created by Bristol's intentionally or recklessly deficient regulatory submissions gave Bristol several extra months to prepare the Liso-cel manufacturing facilities for inspection, the FDA found a litany of basic and easily avoidable deficiencies at both of the facilities where Liso-cel was being manufactured. Indeed, as discussed more fully below, multiple former employees who worked at the facilities responsible for manufacturing Liso-cel confirmed that Bristol knew the facilities were inadequately prepared prior to the FDA inspections and failed to take necessary action to address numerous well-known, but relatively easily solvable, issues that impacted the timing of the FDA's approval of Liso-cel.

[1] The FDA Biologics Expert was a senior reviewer and lead inspector in the Division of Manufacturing and Product Quality at the Center for Biologics Evaluation and Research, Food and Drug Administration, the Division responsible for drugs like Liso-cel. While at the FDA, the FDA Biologics Expert led inspections of manufacturing facilities, including numerous pre-licensing inspections for facilities producing biological products such as cell and gene therapies. The FDA Biologics Expert also reviewed regulatory submissions for such products, including leading reviews of the CMC sections of BLAs. The FDA Biologics Expert's current job as a consultant for pharmaceutical companies includes leading mock audits of manufacturing facilities preparing for pre-licensing inspections by the FDA, including for cell and gene therapy (*i.e.* CAR-T) biologics like Liso-cel.

Moreover, both the FDA Form 483 and the Establishment Inspection Reports for both the Juno and Lonza facilities demonstrate that senior level Bristol employees—including numerous Vice Presidents and Directors of Quality and Manufacturing Groups at Bristol—were fully aware of the many deficiencies that existed and voiced no objections to the deficiency findings of the FDA Investigators.[2] According to the FDA Biologics Expert, the FDA's inspection reports for both facilities noted basic deficiencies of the sort that any large pharmaceutical company like Bristol could have avoided with adequate and typical preparation. Instead of addressing these concerns, however, Defendants ignored them and then intentionally assigned employees with insufficient experience to prepare the facilities, essentially guaranteeing the failure of the FDA inspection and delay of FDA approval for Liso-cel.

6. As the 10(b) Defendants knew, addressing these manufacturing deficiencies would require supplemental regulatory submissions and necessarily delay FDA approval of Liso-cel. But, even those supplemental submissions were deficient and required further supplementation.

7. This unprecedented and inexcusable string of deficiencies in the Liso-cel approval process pushed FDA approval 36 days beyond the Milestone date, just long enough to spare Bristol a highly material $6.4 billion payout to CVR holders, while allowing it to reap the economic benefits of bringing the lucrative drug to market after a modest delay.

8. This is not a case involving a company predicting its drug would be approved only to find the drug did not work as anticipated, after which shareholders claimed the company misled

[2] Among the senior Bristol personnel directly involved in the inspections include are Maria Brown, Vice President of Global Cell Therapy Quality; Ann Lee, Senior Vice President and Head of Cell Therapy Development & Operations; Snehal Patel, Vice President of Cell Therapy Global Manufacturing; Jeffrey Masten, Vice President and Head of Quality; Anne L. Shandy, Director, Quality Systems; Brett A. Johnston, Senior Director, Quality Assurance Operations; Quyen L. Huynh, Director, QC; Frances Browder, Director, QC.

them about the drug's prospects. Rather, here there was a very important drug in development that worked and that the FDA wanted to get approved on an accelerated basis. However, approval by the Milestone deadline of December 31, 2020, would cost Bristol $6.4 billion. Thus, the 10(b) Defendants purposely, by commission and omission, took steps to delay, but not prevent, approval. When the Milestone deadline passed without approval of Liso-cel, investors lost billions. Liso-cel was then approved 36 days after the deadline had passed.

9. Accordingly, Defendants' statements in the Registration Statement, Joint Proxy and throughout the Class Period concerning the "diligent" efforts Bristol would make to meet the Milestones, the likelihood that the Milestones would be met, and the purported value of the CVRs, were materially false and misleading when made.

A. Bristol and Celgene Merge Based on a Materially False and Misleading Registration Statement and Joint Proxy

10. Bristol's merger with Celgene was a historic development in biotechnology, and one of the largest in the history of the industry. The exchange amounted to a $74 billion transaction—$95 billion when accounting for debt—and was intended to launch Bristol into the cutting edge of drug therapy research, development, and manufacturing.

11. From the time the Merger was announced, journalists and analysts alike took note of the enormous pressure that Bristol was under to justify its business decision.[3] While Celgene stockholders were "jubilant" over the deal, Bristol investors were "less than enthused," as the deal required Bristol's paying an over-50% premium on Celgene share prices.[4] In the immediate aftermath of the deal's being announced, Bristol's stock price dropped 12%, as its debt ballooned

[3] *See, e.g.*, Meagan Parrish, *A Glimpse inside Bristol Myers Squibb's integration with Celgene*, PHARMAVOICE (Aug. 1, 2022).

[4] Angelia LaVito and Berkeley Lovelace Jr., *Bristol-Myers Squibb's $74 billion acquisition of Celgene would combine two troubled companies*, CNBC (Jan. 3, 2019).

from just over $7 billion to nearly $40 billion.

12. The Merger consumed enormous resources at the top of Bristol. Countless Board meetings and investor calls transpired, extensive negotiations with Celgene took place, and Board-level committees were set with the explicit purpose of integrating Celgene's technologies within Bristol's existing infrastructure and overseeing the FDA approval process for the Celgene drugs that were the subject of the CVR.

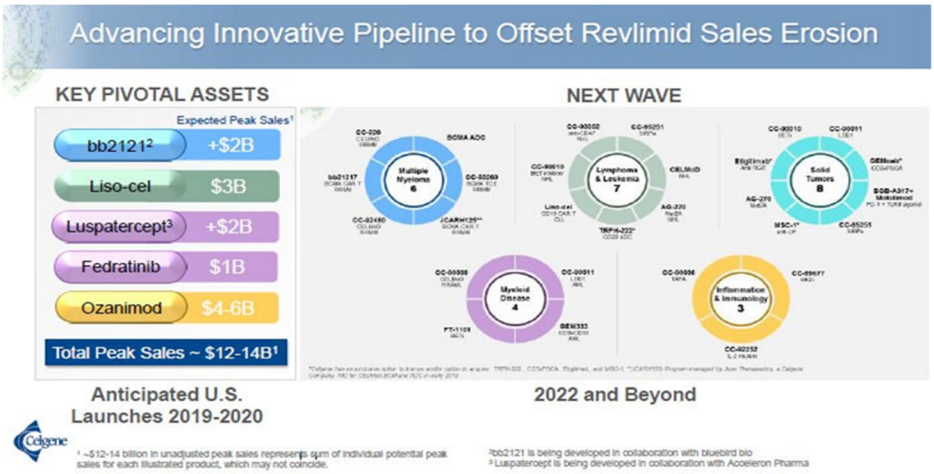
13. The Individual Defendants were intimately involved in negotiating the deal and spoke regularly about the terms of the Merger, the drugs that Bristol would be acquiring as part of the deal and the status of the regulatory approval process of Celgene's drugs, including Liso-cel. For example, at healthcare conferences and before Congress, Bristol CEO Caforio regularly touted both how the Merger would make Bristol the "number one oncology franchise", and the promise of Celgene's drugs. Similarly, Bristol's Chief Medical Officer of Global Drug Development, Samit Hirawat, spoke of Celgene drugs' success at conferences, investor webcasts, and earnings calls. Even Bristol Board of Directors told the public that the acquisition of Celgene's drugs left both companies well-positioned for the long-term. They planned to re-brand Bristol—complete with new logos and "values" —to usher in a "new company, a new BMS."[5]

14. In short, all eyes in the healthcare space—and especially those within Bristol—were on the integration of Celgene and, of course, the approval of its revolutionary drugs, including Liso-cel.

15. Critical to Bristol's decision to pursue an acquisition of Celgene was Celgene's robust pipeline of five late-stage, near-term drugs slated for imminent FDA approval. These drugs were expected to generate upwards of $15 billion in annual revenue.

[5] Parrish, *supra* note 3.

16. In the months preceding the Merger, five pipeline drugs were touted as "Key Pivotal Assets":



17. One of the most important of these late-stage, near-term pipeline drugs was Liso-cel, a revolutionary Chimeric Antigen Receptor ("CAR") immunotherapy designed to train T-cells ("CAR-T" or "CAR T") to recognize and attack specific proteins on cancer cells for use in patients with relapsed or refractory B-cell Non-Hodgkin's lymphoma. The development of Liso-cel was so crucial to the treatment of such cancer that the FDA designated it as both a "Breakthrough Therapy" and a "Regenerative Medicine Advanced Therapy." Both designations meant that Liso-cel would receive an expedited review process by a dedicated team of senior FDA personnel to ensure it would enter the market quickly and start saving and prolonging lives as soon as possible.

18. Prior to the Merger, Celgene was "on track" for submitting the Biologic License Application ("BLA") for Liso-cel – the key regulatory submission for FDA approval of a biologic – "in the second half of 2019 with an expected U.S. approval in mid-2020." The Liso-cel BLA would "include a robust data package containing substantial follow-up on the relapsed/refractory diffuse large B-cell lymphoma cohort." Thus, ***at the time the Merger was announced, Liso-cel was well on its way to securing expedited approval from the FDA***.

19. The valuation of Liso-cel, along with Celgene's other pipeline drugs, was the central point of contention in Merger negotiations between Bristol and Celgene. Determining the value of Liso-cel and Celgene's other pipeline drugs necessarily required extensive diligence by Bristol and the Individual Defendants regarding the likelihood of their approval by the FDA, the status of the regulatory approval process and the timetable by which the drugs were likely to be approved.

20. In December 2018, Bristol and Celgene reached an impasse over the value of Celgene's pipeline. To resolve this disagreement, Bristol (specifically, its CEO, Defendant Caforio) suggested at a December 27, 2018, meeting that the parties explore the possibility of issuing CVRs to current Celgene shareholders payable by Bristol, in addition to the cash and stock components of the Merger consideration.

21. In response and consistent with industry practice, Celgene proposed structuring the CVR agreement to provide a separate payout to CVR holders upon FDA approval of each of Celgene's five near-term, late-stage pipeline assets. Under this structure, CVR holders would be entitled to a $2 payout upon FDA approval of each drug, for a total potential payout of $10. The CVRs would not terminate if Bristol failed to achieve FDA approval for one or two drugs.

22. But Bristol flatly refused Celgene's proposed CVR structure, stating it was unwilling to pay ***any*** amount under a CVR agreement unless ***multiple*** milestones were ***all*** achieved before specified dates. Specifically, at the behest of the Bristol Board, including Defendants Sato, Arduini, Bertolini, Emmens, Grobstein, Lacy, Paliwal, Samuels, Storch, and Vousden, Defendant Caforio personally insisted on an unusual "All or Nothing" provision being included in the Merger agreement with Celgene. Under this atypical "all-or-nothing" approach, Bristol would make a payout of $9 to each CVR holder only if three of Celgene's near-term, late-stage pipeline assets—

(i) JCAR017 a/k/a Liso-cel, (ii) Ozanimod and (iii) bb2121 a/k/a Ide-cel—were all approved prior to a Milestone date of December 31, 2020.

23. Celgene ultimately acceded to Bristol's demands after convincing Bristol to extend the Milestone date for Ide-cel to March 31, 2021 (while keeping the Liso-cel and Ozanimod Milestone dates on December 31, 2020). Obviously, Celgene believed that December 31, 2020, was more than a sufficient amount of time for Liso-cel to receive FDA approval given its belief that approval would be received by mid-2020, and also given that Celgene shareholders' financial stake in the CVR payout gave them a financial incentive to agree only to a Milestone that Celgene expected would be met.

24. A Form CVR Agreement ("CVR Agreement") was included in the Registration Statement (filed on or around February 20, 2019, and signed by Defendants Caforio, Bancroft, Santiago, Sato, Arduini, Bertolini, Emmens, Grobstein, Lacy, Paliwal, Samuels and Storch) and Joint Proxy (which was included in the Registration Statement and also filed separately on February 22, 2019, and signed by Defendant Caforio). It falsely represented that Bristol would use "***diligent efforts***"[6] to achieve approval of the three Celgene near-term, late-stage assets covered by the CVR—*i.e.*, Liso-cel, Ide-cel and Ozanimod. Bristol's "diligent efforts" would include "***such effort and employ[] such resources normally used by such person or entity in the exercise of its reasonable business discretion relating to the research, development or commercialization of***" these Milestone drugs. The CVR Agreement further represented to investors that Bristol's efforts to achieve the Milestones would be benchmarked objectively against other drugs with "similar market potential at a similar stage in its development or product life."

25. In reliance on these and other false and misleading representations in the Joint

[6] Emphases in quotes added throughout, unless noted otherwise.

Proxy, Celgene shareholders overwhelmingly voted to approve the Merger on April 12, 2019. The transaction closed on November 20, 2019, with existing Celgene shareholders receiving one CVR valued at $9, along with one share of Bristol common stock and $50 in cash, for each share of Celgene common stock owned.

B. Bristol Assumes Control of Celgene and Files a Materially Deficient Chemistry, Manufacturing and Controls Portion of Liso-cel's BLA

26. Celgene submitted the first component of the Liso-cel BLA to the FDA on September 30, 2019, fifty-one days before the Merger became effective. There were no issues with this portion of the application. Immediately after the Merger closed, Bristol assumed control of the regulatory approval process for Liso-cel. The next step in the FDA regulatory process was submission of the Chemistry, Manufacturing and Controls ("CMC") portion of the BLA to the FDA. According to the FDA Biologics Expert, this process necessarily required the involvement of numerous senior level Bristol and Celgene personnel, including from Bristol's regulatory affairs office. As the FDA provides publicly available information regarding how it reviews CMC submissions, Bristol had ample opportunity to staff its teams in preparation for its Liso-cel submission and ensure the CMC met the FDA's requirements.

27. On December 18, 2019—three full months after the submission of the first component of the BLA application—Bristol finally submitted the CMC portion of the BLA to the FDA. According to the FDA Biologics Expert, this three-month delay is unjustifiable and highly unusual. The information included in the CMC would have been known by both Celgene and Bristol at the time the first component was submitted to the FDA. As such, and given that the CMC is ***the most important*** section of the BLA, a pharmaceutical giant like Bristol normally would have filed the CMC immediately following the closing of the Merger.

28. Bristol issued a press release on December 18, 2019, announcing its submission of

the final portion of the BLA for Liso-cel. This press release omitted to disclose a key, material fact: that the CMC portion of the BLA that Bristol had submitted was materially—and obviously—deficient.

29. The FDA provisions governing the CMC portion of BLAs obligate applicants to "include a full description of the manufacturing process, including analytical procedures that demonstrate the manufactured product meets prescribed standards of identity, quality, safety, purity, and potency" and provide that the substantiating data "must be available to establish that the analytical procedures used in testing meet proper standards of accuracy, sensitivity, specificity, and reproducibility and are suitable for their intended purpose." According to the FDA Biologics Expert, these requirements are familiar to any pharmaceutical executive who was responsible for submitting biologics to the FDA for approval, and certainly would have been well known to multitudes of senior officers working at Bristol. Indeed, according to the FDA Biologics Expert, Bristol, Celgene and Juno would have each had regulatory affairs, CMC and clinical teams who were available to oversee different portions of the BLA submission. Moreover, as the acquiring company, it would have been solely Bristol's prerogative as to how to allocate its resources for the submission. Most critically, according to the FDA Biologics Expert, any pharmaceutical executive who worked on submitting biologics to the FDA would have known that it was incredibly important for the BLA application to contain all the required data and information, not simply "summaries".

30. As subsequently revealed in regulatory documentation released by the FDA, however, in direct contravention of these basic guidelines, the CMC portion of the Liso-cel BLA submitted by Bristol in December 2019 only included "summaries" of assays (*i.e.*, tests used to ensure the drug is safe and efficacious) and platform validations performed at contract testing

organizations that the FDA later deemed "***inadequate to understand and assess control of the analytical procedures and respective validations***." These and other failures were detailed in the final CMC BLA Review Memorandum from the FDA's Center for Biologics Evaluation and Research:

> Juno received a Major Amendment Acknowledgement letter from the FDA on 05/05/2020 due to information submitted for review in Amendment 31 (received on 04/15/2020). Amendment 31 included analytical procedures and validation reports for all (b) (4) tests performed at (b) (4), with the exception of 2 validation reports provided in Amendment 51 (received on 04/29/2020). The original BLA submission contained, in most cases, summaries of assays and platform validations performed at contract testing organizations, which was inadequate to understand and assess control of the (b) (4) analytical procedures and respective validations.

31. According to the FDA Biologics Expert, any pharmaceutical executive who worked on submitting biologics to the FDA would have known that submitting mere summaries of assays and platform validations in a BLA would be deemed by the FDA to be insufficient and delay the approval process. This was a "big mistake."

32. Following the late and intentionally or recklessly wholly inadequate CMC submission, Bristol then compounded its errors by intentionally or recklessly causing one inexcusable delay after another, all while falsely representing in statements to investors that it was working diligently to meet the Milestone date for Liso-cel approval and that doing so was in Defendants' financial interest. On April 15, 2020, Bristol submitted Amendment 31 to the Liso-cel BLA remedying the CMC defects identified by the FDA. Just as above, the team in charge of remedying the CMC defects would necessarily have included senior personnel from the regulatory affairs, CMC and clinical teams of Bristol, Celgene and Juno. The additional information contained in Bristol's Amendment 31, however, was so significant that it unsurprisingly prompted the FDA to issue a Major Amendment Acknowledgment on May 5, 2020. As explained by the

FDA Biologics Expert, such a step is rarely taken by the FDA, particularly where, as here, a therapy has received a "Breakthrough" designation, and was only issued because Amendment 31 was so substantial.

33. The Major Amendment Acknowledgement had two substantive results that dramatically affected the ability to receive FDA approval of Liso-cel by the Milestone date of December 31, 2020.

34. First, the Major Amendment Acknowledgment automatically extended the FDA's Prescription Drug User Fee Act ("PDUFA") target approval deadline (*i.e.*, the FDA's target approval date for the therapy) by three months, from August 17, 2020 to November 16, 2020 – *just forty-five days before the Liso-cel Milestone deadline*.

35. Second, the Major Amendment Acknowledgement necessarily prompted the FDA to reschedule its planned Pre-License inspection of Liso-cel's two manufacturing facilities—the Juno facility in Bothell, Washington (the "Juno Facility") and the Lonza Group AG facility in Houston, Texas (the "Lonza Facility")—from June 2020 to October and December 2020, respectively.

36. Bristol's failure to submit a passable BLA was not by mistake. Indeed, both prior to and following the Merger, the Individual Defendants were intimately involved in monitoring the problems and progress of Liso-cel and the rest of the Milestone Drugs. Specifically, Defendant Caforio and Defendant Hirawat both evidenced detailed, up to the minute, understanding of where Liso-cel and the other Milestone Drugs were in the approval process and the issues they were facing in multiple presentations to investors and (in the case of Caforio), a presentation to Congress.

37. Defendants Arduini, Emmens, Paliwal, and Vousden were also intimately involved

in overseeing the regulatory process for approval of Liso-cel. For example, Bristol's Science & Technology Committee, on which Defendants Sato, Arduini, Emmens, and Vousden served, and which met twenty times during the Liso-cel approval process, was responsible for overseeing Bristol's research and development ("R&D") and pipeline of new pharmaceuticals. According to the Science & Technology Committee's 2019 Charter, as well as Bristol's public SEC filings, the Science & Technology Committee was responsible for, among other things: (1) overseeing and regularly reviewing Bristol's pipeline; (2) assisting in setting pipeline performance metrics under the Company's incentive compensation programs and reviewing performance results; and (3) advising Bristol's Board on the Company's progress in achieving near-term and long-term R&D goals; and (4) coordinating with the Integration Committee in overseeing the Company's integration of Bristol and Celgene's pipelines into a combined portfolio.

38. Following the Merger, the Science & Technology Committee also worked with the Integration Committee, which Defendants Caforio, Arduini, Emmens, Paliwal, and Vousden sat on and which met nine times during the Liso-cel approval process, to "oversee[] the company's progress towards integrating the company's and Celgene's pipelines and alliances into a combined portfolio, and monitoring portfolio prioritization and execution." Bristol's Integration Committee was responsible for overseeing all aspects of the Celgene integration and providing advice and assistance to Bristol's management with respect to the integration. According to proxy statements filed by Bristol with the SEC, the Integration Committee's responsibilities included: (1) overseeing the Company's progress in achieving launch readiness and commercial execution for the near-term product launch opportunities; (2) working with the Science & Technology Committee to oversee the Company's progress towards integrating Celgene's pipeline and monitoring portfolio prioritization and execution; and (3) providing regular reports to the Board on the progress of the

Merger integration, including at each regularly scheduled Board meeting.

39. It was the job of both the Science and Technology Committee and the Integration Committee to keep Bristol's executives abreast of any developments regarding the approval process for Liso-cel and the rest of the Milestone Drugs.

40. Thus, the top management of Bristol, which sat on either or both of these two Committees, were fully aware and knowledgeable of the FDA submission delays and deficiencies, as well as the many deficiencies at the Juno and Lonza facilities, which were highly likely to prevent FDA approval of Liso-cel by the Milestone deadline of December 31, 2020.

41. Additionally, the FDA communicated extensively and directly with Bristol and its senior executives, including, among others, Defendants Caforio, Arduini, Emmens, Paliwal, and Vousden, throughout the approval process of Liso-cel. Through these communications and their own responsibilities in overseeing the FDA regulatory approval process, these Defendants and other Bristol senior executives learned about the status of its review of the BLA, the delays caused by the Major Amendment, the original and amended PDUFA dates, and the many deficiency at the Lonza and Juno facilities and in Bristol's FDA responses. Moreover, letters exchanged between the FDA and Bristol cc'ed identified as many as ***forty*** individuals at Bristol, including senior executives from Global Regulatory Sciences, Global Risk Management, Global Drug Development, and Global Development Operations, who were made aware of the issues with the FDA submissions and site inspections. Similarly, ***dozens*** of Bristol employees attended the March and September 2020 meetings with the Center for Biologics Evaluation and Research ("CBER"), including representatives from Bristol's divisions of Global Drug Development; Global Regulatory Sciences; Global Risk Management; Global Drug Safety; Global Medical Affairs; and Global Development Operations. These individuals were all regulatory specialists who would be

expected to submit an adequate application as part of the BLA process, and who, as the FDA Expert explained, would have reported to Bristol's regulatory affairs executive throughout the regulatory approval process.

C. Bristol Fails to Properly Prepare Its Manufacturing Facilities for Inspection and then Causes Further Delay by Filing Inadequate Responses to the FDA's Findings of Deficiencies at the Manufacturing Facilities

42. Liso-cel's "major amendment" designation automatically triggered the three-month extension of the FDA's target review date — from August 17, 2020, to November 16, 2020, only six weeks before the December 31, 2020, Liso-cel Milestone date. The rescheduling of the outside approval date—leaving only a short window directly coinciding with the winter holidays when workforces are typically reduced to conduct the inspections of Liso-cel's manufacturing facilities—resulting from the Major Amendment Acknowledgment made it highly unlikely that Liso-cel would be approved prior to the Milestone deadline and that, as a result, the CVRs would become payable.

43. Nonetheless, Bristol continued to assure CVR investors that it was confident that Liso-cel would be approved by the Milestone deadline, with Defendant Hirawat stating on May 7, 2020, that "we're truly looking forward to get approval of this therapy towards the end of the year," and Defendant Caforio telling investors on June 25, 2020, that "we feel really good about where we are from a regulatory perspective. So that applies to products that may be included in the CVR as well as the rest of the portfolio." Neither Hirawat nor Caforio could have uttered these false statements to the public without having been informed about the state of Liso-cel's FDA approval process.

44. In addition, to the significant delay caused by the Major Amendment, documents subsequently released by the FDA demonstrate that Bristol failed to use the additional time resulting from the delay to ensure that the relevant facilities were sufficient to pass inspection.

Former employees at the two Liso-cel manufacturing facilities, Lonza and Juno, revealed that there were pervasive and obvious issues with the facilities warehouse that had existed for months, if not years, ***prior*** to the scheduled inspection, which Bristol knew or would have known about based on, *inter alia*, its 2019 pre-approval inspections.

45. Many of these well-known problems were ultimately identified by the FDA following its inspections. Specifically, the FDA issued a Form 483—an inspection report on violations of FDA requirements—for each facility. These Form 483s reveal that when the inspections of Liso-cel's manufacturing facilities were conducted, the FDA identified myriad basic manufacturing and quality control problems requiring a response and remediation plan by Bristol. *See infra* ¶¶ 141-166. Yet, the Defendants continued to make false and misleading statements to investors about the approval process and the facilities inspections that omitted the known pervasive manufacturing facilities problems and reassured investors that they were diligently pursuing regulatory approval and would likely be able to obtain approval prior to the Milestone deadline.

46. According to the FDA Biologics Expert, knowledge of the Form 483 would have proliferated throughout Bristol. On-site Bristol staff and Bristol senior executives would have been the first to be made aware of the deficiencies at the "closing meeting." Consistent with that typical practice, according to the FDA's inspection report, Maria Brown, Vice President of Cell Therapy Development and Operations Quality at Bristol, was present for these closing meetings.

47. Moreover, CW #9, a former Bristol employee who was part of a team that contributed updates to senior management in 2020, stated that Defendant CEO Caforio and his co-executive defendants would have been aware of underlying issues regarding the FDA approval process for Liso-cel, including Form 483s from the FDA and any delay induced by a major amendment. Similarly, CW #10, stated that Caforio "should have been apprised of the situation"

and should have known about all such FDA communications.

48. Regulatory documents subsequently released in connection with Liso-cel further reveal that the FDA found Bristol's responses to the FDA about its facilities – despite the considerable personnel Bristol devoted to the inspection—were "***unclear***" with "***questionable points identified***." According to the FDA Biologics Expert, it was clear from the start that these responses were inadequate, because rather than providing a comprehensive plan for how the Company planned to address the FDA's observations as is standard, Bristol responded with "fluff" by pointing the FDA to Standard Operating Procedures which the FDA had already reviewed and found inadequate. Moreover, Bristol delayed supplementing its Lonza responses until December 18, 2020—just two weeks before the outside date on the Liso-cel Milestone. The FDA subsequently stated that "***there were outstanding concerns from the [Juno] facility inspection prior to the action due date***."

49. According to the FDA Biologics Expert, these requirements would be familiar to any competent pharmaceutical executive involved in biologic drug approval, including Bristol's Vice President of Cell Therapy Development and Operations Quality, Maria Brown, Chief Quality Officer and Senior Vice President of Global Quality, Jackie Elbonne, and Senior Vice President of Global Regulatory Affairs, Jocelyn Seymour, as well as the ten regulatory affairs specialists who were directly involved in corresponding with the FDA about Liso-cel. Further, as the FDA Biologics Expert explains, any competent pharmaceutical executive involved in biologic drug approval would also understand the importance of submitting this basic information to the FDA and the consequences if a pharmaceutical company did not do so. No one, much less an experienced drug company like Bristol, would ever have omitted such key information had they truly intended to use "diligent efforts" to obtain FDA approval of Liso-cel by the Milestone date.

This is particularly true where, as here, the omitted data was so incredibly favorable to Liso-cel as an effective therapeutic. It is implausible that one competent regulatory affair specialist would have accidentally omitted this critical data from the FDA submission and inconceivable that ten regulatory specialists would not have noticed the omission of this basic, favorable data.

D. The COVID-19 Pandemic was Not Responsible for the Missed Milestone

50. Bristol's actions in connection with the approval of Liso-cel were also commercially unreasonable when compared to its prior practices and industry peers.

51. Instead of acknowledging that it had intentionally or recklessly caused delays throughout the FDA approval process, Bristol blamed the COVID-19 pandemic for causing it to miss Liso-cel's Milestone date. Yet, a comparison of the approval process for Liso-cel to that of other drugs during the COVID-19 pandemic demonstrates that COVID-19-related inspection delays were not the reason Liso-cel missed the Milestone. The data show that Liso-cel was a major outlier, even when compared to other drugs of its type and other drugs approved during the COVID-19 pandemic. The time between submission of the BLA and FDA approval for Liso-cel was 415 days—nearly twice as long as the three other CAR-T therapies approved in recent years, including a rival therapy for which the BLA was submitted a week before the Liso-cel BLA, but which received FDA approval seven *months* before Liso-cel, and which also would have been impacting by any supposed COVID-19 delays. The timeline from submission to approval for Liso-cel was also two months longer than that of *any* other original therapy submitted by Celgene or Bristol over the previous six years—and nearly twice the average. The Company achieved such delay in part by submitting *ninety-six* amendments to its BLA, a substantial magnitude more than were submitted for rival CAR-T therapies.

52. According to the FDA Biologics Expert, to conduct an apples-to-apples comparison, one should consider ***all parenteral cell/gene therapy biologics (Advanced Therapies)***

approved by FDA/CBER/Office of Tissues and Advanced Therapies ("OTAT") at the time Liso-cel was approved, and during the pandemic, except for tissue type products (non-parenteral), and cord blood (minimally manipulated) as these are not Advanced Therapies, and except for those manufactured outside of the U.S. where FDA/Team Biologics was not inspecting at the time. After excluding those biologics, one is left with biologics that are directly comparable to Liso-cel, because they all undergo identical approval processes within CBER and OTAT and were inspected by Team Biologics in-person and CBER virtually at the time, like Liso-cel, a parenteral product. With this in mind, according to the FDA Biologics Expert, ***Bristol's eleven-month approval timeline for Liso-cel is a statistical anomaly when weighed against these comparators.*** Strikingly, by including non-priority review biologics in this analysis, the FDA Biologics Expert actually ***overestimated the approval time for Liso-cel comparators.*** Moreover, according to CW #10, who was an executive in the quality department at Celgene/Bristol, Bristol cannot blame the delay of approval of Liso-cel on COVID-19 alone, because even after the FDA inspected the Lonza facility, it *still* did not pass inspection.

E. Liso-cel is Approved by the FDA Just 36 Days After the Milestone Deadline and Bristol Avoids Paying CVR Holders Billions

53. On December 31, 2020, the Milestone date for Liso-cel lapsed and the CVRs were terminated, destroying $6.4 billion in value for CVR holders. The FDA approved Bristol's BLA for Liso-cel just 36 days later. Despite its repeated delinquency in timely responding to FDA requests for further information both in its BLA submission and in response to FDA Form 483s identifying significant issues at the Juno and Lonza facilities, Bristol falsely placed the blame solely on COVID-19-related plant inspection delays.

II. JURISDICTION AND VENUE

54. The claims asserted herein arise under Sections 10(b), 14(a), and 20(a) of the

Exchange Act, 15.U.S.C. §§ 78n(a), 78t(a), Rules 10b-5 and 14a-9 promulgated thereunder by the SEC, 17 C.F.R. § 240.10b-5 and 17 C.F.R. § 240.14a-9, and Sections 11(a),12(a)(2), and 15 of the Securities Act.[7]

55. This Court has jurisdiction over these claims pursuant to 28 U.S.C. §§ 1331 and 1337, Section 27 of the Exchange Act, and Section 22 of the Securities Act.

56. Venue is proper in this District pursuant to Section 27 of the Exchange Act, Section 22(a) of the Securities Act, and 28 U.S.C. § 1391(b), given that many of the acts and practices complained of herein occurred in this District, as Bristol's corporate headquarter is in this District and the CVRs were traded on the New York Stock Exchange.

57. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications and the facilities of the national securities markets.

III. PARTIES

A. Plaintiffs

58. Lead Plaintiff Mangrove Partners Master Fund, Ltd. purchased CVRs during the Class Period. Plaintiff suffered damages as a result of the violations of the federal securities laws alleged herein. See ECF No. 63-1 (Certification).

59. Plaintiff Ehab Khalil exchanged his Celgene shares and received the CVRs as partial consideration in connection with the Merger and purchased CVRs during the Class Period. See *Khalil v. Bristol-Myers Squibb et al.*, Case 1:21-cv-08255-JMF, ECF No. 1 at 74

[7] While we recognize that the Court dismissed Plaintiffs' Securities Act claims with prejudice, we are retaining them in the operative pleading for potential appellate purposes.

(Certification). Plaintiff suffered damages as a result of the violations of the federal securities laws alleged herein.

60. Plaintiff SM Merger/Arbitrage, L.P. exchanged its Celgene shares and received the CVRs as partial consideration in connection with the Merger and purchased CVRs during the Class Period. See ECF Nos. 67-1, 86-1 (Certification). Plaintiff suffered damages as a result of the violations of the federal securities laws alleged herein.

61. Plaintiff SM Investors, L.P. exchanged its Celgene shares and received the CVRs as partial consideration in connection with the Merger and purchased CVRs during the Class Period. See ECF Nos. 67-1, 86-1 (Certification). Plaintiff suffered damages as a result of the violations of the federal securities laws alleged herein.

62. Plaintiff SM Investors II, L.P. exchanged its Celgene shares and received the CVRs as partial consideration in connection with the Merger and purchased CVRs during the Class Period. See ECF Nos. 67-1, 86-1 (Certification). Plaintiff suffered damages as a result of the violations of the federal securities laws alleged herein.

B. Corporate Defendant

63. Defendant Bristol is a Delaware corporation, with its principal executive offices located at 430 East 29th Street, 14th Floor, New York, New York 10016. Bristol's common stock is listed and actively traded on the NYSE under the ticker symbol "BMY." Bristol is one of the world's largest pharmaceutical companies and is consistently ranked on the Fortune 500 list of the largest U.S. corporations. In 2021, it had total revenue of $46.4 billion.

C. Individual Defendants

1. Section 10(b) Individual Defendants

64. The following Defendants are subject to the claims brought under Section 10(b) of the Exchange Act (and Rule 10b-5 promulgated thereunder), as well as the claims brought under

Section 20(a) of the Exchange Act.

65. Defendant Giovanni Caforio has served as Bristol's Chief Executive Officer since 2015. Caforio signed the Registration Statement and Joint Proxy filed with the SEC in connection with the Merger, as well as the Forms 10-Q and Form 10-K filed by Bristol in 2020 that contained false and misleading statements and omissions. He is also a Section 20(a) Defendant. Caforio served on Bristol's Integration Committee from 2019 to 2020.

66. Defendant Samit Hirawat has served as Bristol's Executive Vice President, Chief Medical Officer, Global Drug Development, since 2019. He made several false and misleading statements and omissions during conference calls and presentations to investors during the Class Period. He is also a Section 20(a) Defendant.

2. Section 14(a), Section 11 And Section 15 Individual Defendants

67. The following Defendants are subject to the claims brought under Section 14(a) of the Exchange Act (and Rule 14a-9 promulgated thereunder), as well as the claims brought under Section 20(a) of the Exchange Act. They are also subject to claims brought under Section 11 and Section 15 of the Securities Act. Each signed the false and misleading Registration Statement, and the Proxy Statement was made on their behalf.

68. Defendant Caforio, described above.

69. Defendant Vicki L. Sato served as Bristol's Lead Independent Director at all relevant times and served on the Science & Technology Committees. She is also a Section 20(a) Defendant.

70. Defendants Peter J. Arduini served as a Director of Bristol at all relevant times and served on the Integration Committee and the Science & Technology Committee. He is also a Section 20(a) Defendant.

71. Defendant Robert Bertolini served as a Director of Bristol at all relevant times.

He is also a Section 20(a) Defendant.

72. Defendant Matthew W. Emmens served as a Director of Bristol at all relevant times and served on the Integration Committee and the Science and Technology Committee. He is also a Section 20(a) Defendant.

73. Defendant Michael Grobstein served as a Director of Bristol at all relevant times. He is also a Section 20(a) Defendant.

74. Defendant Alan J. Lacy served as a Director of Bristol at all relevant times. He is also a Section 20(a) Defendant.

75. Defendant Dinesh C. Paliwal served as a Director of Bristol at all relevant times and served on the Integration Committee. He is also a Section 20(a) Defendant.

76. Defendant Theodore R. Samuels served as a Director of Bristol at all relevant times. He is also a Section 20(a) Defendant.

77. Defendant Gerald L. Storch served as a Director of Bristol at all relevant times. He is also a Section 20(a) Defendant.

78. Defendant Karen H. Vousden served as a Director of Bristol at all relevant times and served on the Integration Committee and on the Science and Technology Committee. She is also a Section 20(a) Defendant.

3. Additional Sections 11 And 15 Individual Defendants

79. In addition to the Individual Defendants described above in Section III.A.2, the following Individual Defendants set forth below are subject to the claims brought under Sections 11 and 12 of the Securities Act:

80. Defendant Charles Bancroft was Bristol's Chief Financial Officer prior to being replaced by David V. Elkins in June 2019. He signed the false and misleading Registration Statement.

81. Defendant Karen M. Santiago was Bristol's Principal Accounting Officer. She signed the false and misleading Registration Statement.

* * *

82. All the Defendants set forth above are referred to collectively herein as the "Individual Defendants."

IV. FACTUAL BACKGROUND

A. Celgene Acquires Juno Therapeutics in 2018 to Develop its Flagship CAR-T Therapy Liso-cel

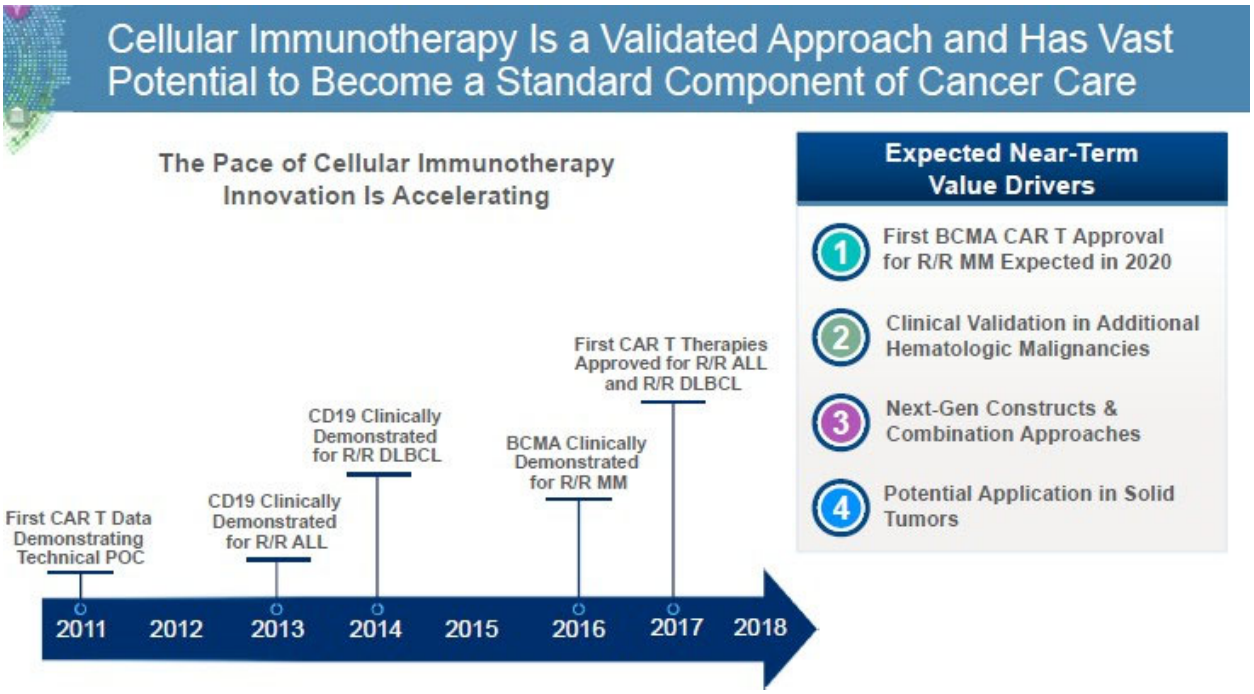
83. Prior to its acquisition by Bristol, Celgene was a global biopharmaceutical company engaged primarily in the discovery, development, and commercialization of innovative therapies for the treatment of cancer and inflammatory diseases. Celgene did so through next-generation solutions in protein homeostasis, immuno-oncology, epigenetics, immunology and neuro-inflammation.

84. Celgene invested substantially in research and development in support of multiple ongoing clinical development programs and, in the first three quarters of 2018, Celgene spent over $2.2 billion, $1.25 billion and $1.08 billion, respectively, on research and development. This research covered disease areas such as hematology, solid tumors, inflammation, and immunology.

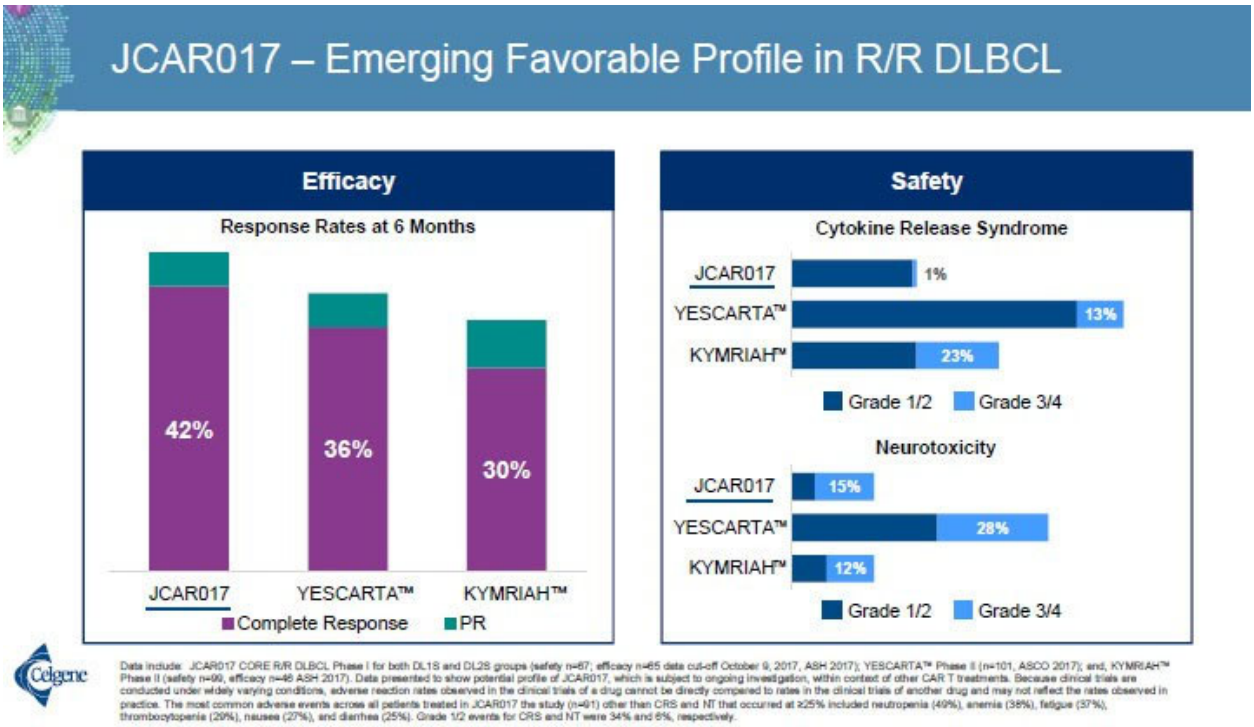
85. In 2018, Celgene sought to expand its immunology division by acquiring a business engaged in the development of products using novel CAR-T therapy. CAR-T is a revolutionary immunotherapy that programs a patient's immune system to recognize and fight cancer. During the treatment process, T-cells are removed from a patient's blood and genetically modified to recognize the patient's cancer cells. The T-cells are then reinfused into the patient for the purpose of recognizing and destroying cancer cells.

86. In January 2018, Celgene announced it had agreed to acquire Juno Therapeutics, a

specialty biopharmaceutical company on the forefront of CAR-T immunotherapy. In the presentation discussing the acquisition, Celgene set forth the expected timeline for FDA approval of Juno's CAR-T candidates as follows:

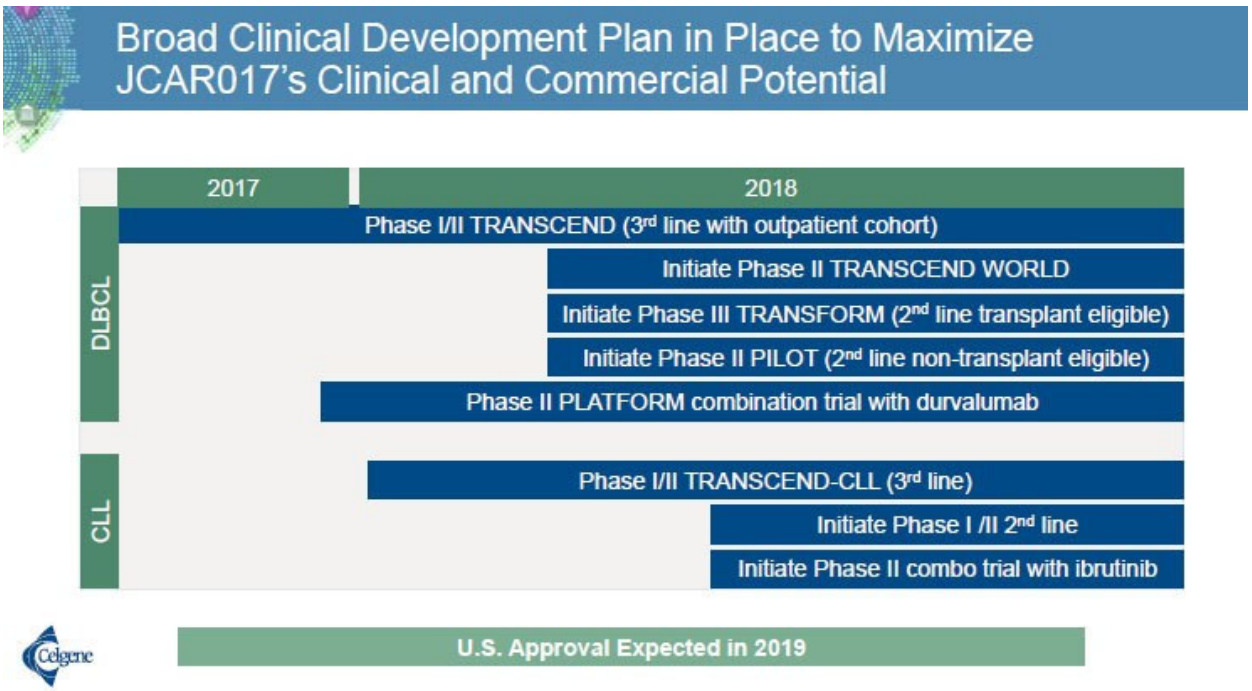


87. In the same presentation, Celgene highlighted the efficacy of Liso-cel relative to other CAR-T therapies developed by competitor biopharmaceutical companies. Liso-cel had a remarkable "Complete Response" rate of 42% versus rivals YESCARTA, with an efficacy rate of 36% and KYMRIAH with an efficacy rate of 30%. The presentation also highlighted Liso-cel's safety profile, including that just 1% of trial participants experienced serious Cytokine Release Syndrome (a common but occasionally serious side effect), more than ten times ***less*** than the rival CAR-T therapies. In other words, Liso-cel worked better and with less negative side effects than its competitors, making it a "best-in-class" drug.



Data include: JCAR017 CORE R/R DLBCL Phase I for both DL1S and DL2S groups (safety n=67; efficacy n=45 data cut-off October 9, 2017, ASH 2017); YESCARTA™ Phase II (n=101, ASCO 2017); and, KYMRIAH™ Phase II (safety n=99, efficacy n=46 ASH 2017). Data presented to show potential profile of JCAR017, which is subject to ongoing investigation, within context of other CAR T treatments. Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. The most common adverse events across all patients treated in JCAR017 the study (n=91) other than CRS and NT that occurred at ≥25% included neutropenia (49%), anemia (38%), fatigue (37%), thrombocytopenia (29%), nausea (27%), and diarrhea (25%). Grade 1/2 events for CRS and NT were 34% and 6%, respectively.

88. Celgene's management also set forth a timeline for comprehensive and exhaustive efficacy and response trials for Liso-cel based on its extensive knowledge of Liso-cel and the FDA approval process, stating that ***approval of the drug in the U.S. was expected in 2019***:



B. Prior to Finalization of the Merger, FDA Approval of Liso-cel is on Track to be Completed Prior to the CVR Deadline.

89. In 2016, the FDA designated Liso-cel as a "Breakthrough Therapy," which expedites the development and review process for critical medication. Upon such designation, senior FDA personnel become involved in a proactive, collaborative review of a Breakthrough Therapy throughout its development and provide intensive, interactive guidance to the applicant. The designation allows the FDA to authorize a rolling review of a therapy's marketing application to allow the product to enter the market more quickly. Of the forty-nine cancer therapies with a Breakthrough Therapy designation approved between 2013 and 2020, the average approval occurred two months before the PDUFA date.

90. The FDA also designated Liso-cel as a "Regenerative Medicine Advanced Therapy" in 2017. This designation further expedited the development and review process for Liso-cel. A Regenerative Medicine Advanced Therapy designation provides ways to accelerate the review process further and to satisfy post-approval requirements. The combined result of the Breakthrough Therapy and Regenerative Medicine Advanced Therapy designations is an ultra-expedited development and review process designed to allow the therapy to reach the market quickly so that it can start saving lives as soon as possible.

91. In September 2018, Bristol contacted Celgene to propose a transaction that would result in Celgene becoming a wholly-owned subsidiary of Bristol. The two parties had previously discussed a strategic transaction and Celgene expressed interest in renewing those negotiations. During the ensuing months, the companies began merger negotiations. The main points of contention were Celgene's valuation and whether Bristol would pay for the acquisition with cash, Bristol stock, or some other form of consideration—issues made more complicated by the ongoing declines in the prices of both Celgene's and Bristol's common stock. Bristol's merger with Celgene

was a historic development in biotechnology, and one of the largest in the history of the industry. The exchange amounted to a $74 billion transaction—$95 billion when accounting for debt – and was intended to launch Bristol into the cutting edge of drug therapy research, development, and manufacturing.

92. From the time the Merger was announced, journalists and analysts alike took note of the enormous pressure that Bristol was under to justify its business decision. While Celgene stockholders were "jubilant" over the deal, Bristol investors were "less than enthused," as the deal required Bristol's paying an over-50% premium on Celgene share prices. In the immediate aftermath of the deal's being announced, Bristol's stock price dropped 12%, as its debt ballooned from just over $7 billion to nearly $40 billion.

93. The Merger consumed enormous resources at the top of Bristol. Countless Board meetings and investor calls transpired, extensive negotiations with Celgene took place, and corporate committees were stood up with the explicit purpose of integrating Celgene's technologies within Bristol's existing infrastructure.

94. Moreover, the senior officers at Bristol spoke extensively about the Merger at the time and in the immediate aftermath of the deal. According to Bristol CEO Caforio's statement on the deal, the Merger would make Bristol the "number one oncology franchise." Caforio spoke about the regulatory approval process of the Celgene drugs on earnings calls and to investors. Caforio touted the promise of Celgene's drugs at healthcare conferences and before Congress. Similarly, Bristol's Chief Medical Officer of Global Drug Development, Samit Hirawat, spoke of Celgene drugs' success at conferences, investor webcasts, and earnings calls. The Bristol Board of Directors, at the close of the deal, told the public that the Merger left both companies well-positioned for the long-term. They planned to re-brand Bristol—complete with new logos and

"values" —to usher in a "new company, a new BMS."

95. Prior to its acquisition by Bristol, Celgene informed investors about the timeline for FDA approval of Liso-cel. For example, during a July 26, 2018, conference call, Celgene's Chief Medical Officer Jay Backstrom stated: "In keeping with our goal to be a global leader in cellular immunotherapy, both bb2121 and [L]iso-cel continue to advance and remain top priorities." Mr. Backstrom further stated that, for Liso-cel, "***BLA preparations are underway, and the program remains on track for an expected 2019 approval***." During an October 25, 2018, conference call, Celgene's CEO Mark J. Alles stated, "we are making meaningful progress advancing our late-stage pipeline to high-value inflection."

96. Between June 2018 and January 2019, Celgene slightly shifted back its plan from receiving approval in 2019 to submitting its BLA in 2019. But the expected approval date remained well in advance of December 31, 2020, and Celgene's statements regarding the likelihood of Liso-cel approval continued following its January 2019 announcement of the acquisition by Bristol. On January 31, 2019, during Celgene's call to discuss Fourth Quarter and full year financial results, Celgene's Chief Medical Officer Jay Backstrom stated:

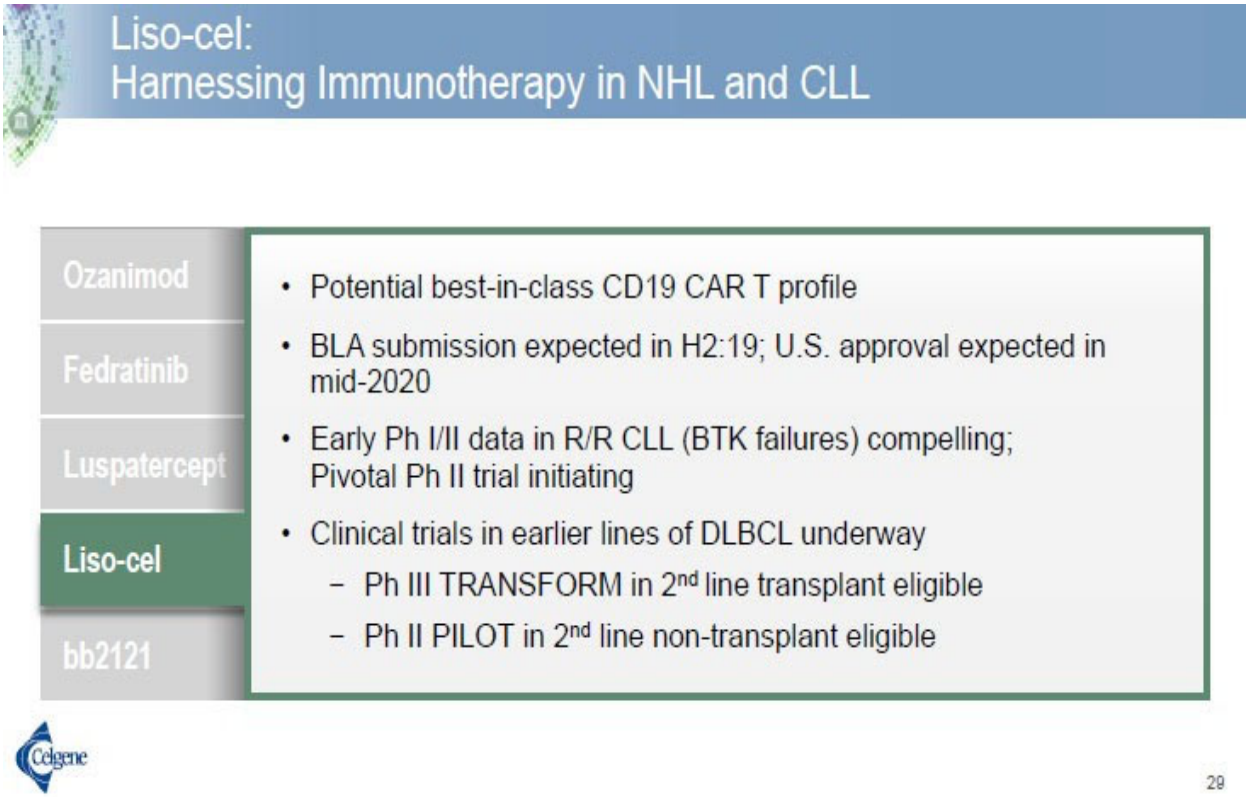
> Now turning to our CAR T programs. Both liso-cel and bb2121 remain on target for expected 2020 approvals. ***For liso-cel, on Slide 29, we remain on track for submitting the BLA in the second half of 2019 with an expected U.S. approval in mid-2020. As we've previously mentioned, the BLA will include a robust data package containing substantial follow-up on the relapsed/refractory diffuse large B-cell lymphoma cohort, allowing further characterization of the duration of response and will include a safety database that will be approaching 300 treated patients by the time of our submission, a safety database that will be 2x to 3x that included in the initial submissions for the 2 approved CD19-directed CAR Ts.*** In addition, we are advancing liso-cel to earlier lines of treatment, with the second- line studies TRANSFORM and PILOT in diffuse large B-cell lymphoma patients who are transplant eligible or nontransplant eligible, respectively.

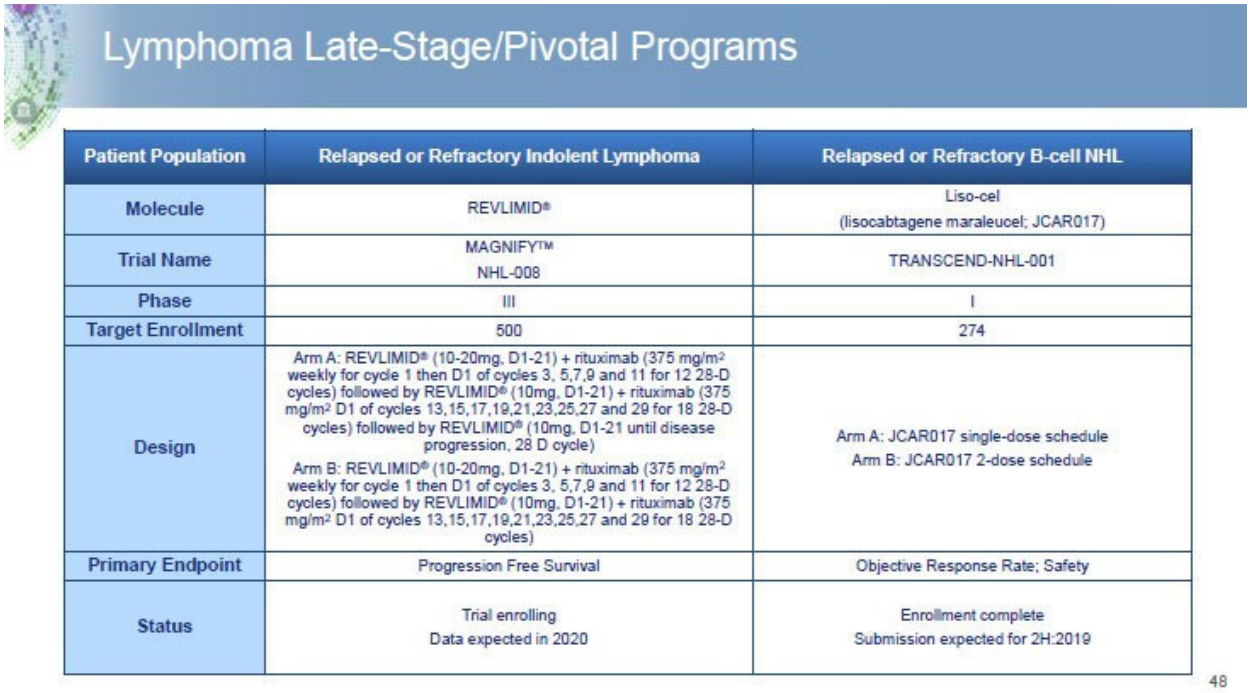
97. The degree to which Celgene's Chief Medical Officer was able to offer detailed insight on the approval status of Liso-cel—down to the exact data package being assembled and

patient population being treated – makes clear that his involvement and knowledge of the approval process was intimate. Celgene's, and ultimately Bristol's, Chief Medical Officers (Defendant Hirawat for Bristol) and other executives were undoubtedly kept abreast of the progress—and ultimately missteps—involved in the approval of Liso-cel.

98. On the same call, Nadim Ahmed (Celgene's President of Global Hematology & Oncology) stated: "***I think everything is on track from a manufacturing process, actually across all of our CAR T programs, both from the clinical trial perspective and the commercial perspective.***" Again, there would be no way for Ahmed to have opined on the status of the developments in Celgene's CAR-T programs – including Liso-cel – without being informed by his staff of said developments. Such a statement is yet another illustration of the constant upward flow of information in Celgene and Bristol.

99. The related slides from the accompanying presentation reiterated that Liso-cel's BLA submission was expected in 2019 and FDA approval was expected in mid-2020. Specifically, the presentation highlighted Liso-cel as a "potential best-in-class CD19 CAR T profile," that Phase I/II trial data was "compelling" and that Celgene expected to submit the BLA in mid-2019, which would enable FDA approval of Liso-cel ***in mid-2020***:


Liso-cel:
Harnessing Immunotherapy in NHL and CLL
Ozanimod
Fedratinib
Luspatercept
Liso-cel
bb2121
• Potential best-in-class CD19 CAR T profile
• BLA submission expected in H2:19; U.S. approval expected in mid-2020
• Early Ph I/II data in R/R CLL (BTK failures) compelling; Pivotal Ph II trial initiating
• Clinical trials in earlier lines of DLBCL underway
– Ph III TRANSFORM in 2nd line transplant eligible
– Ph II PILOT in 2nd line non-transplant eligible
Celgene
29



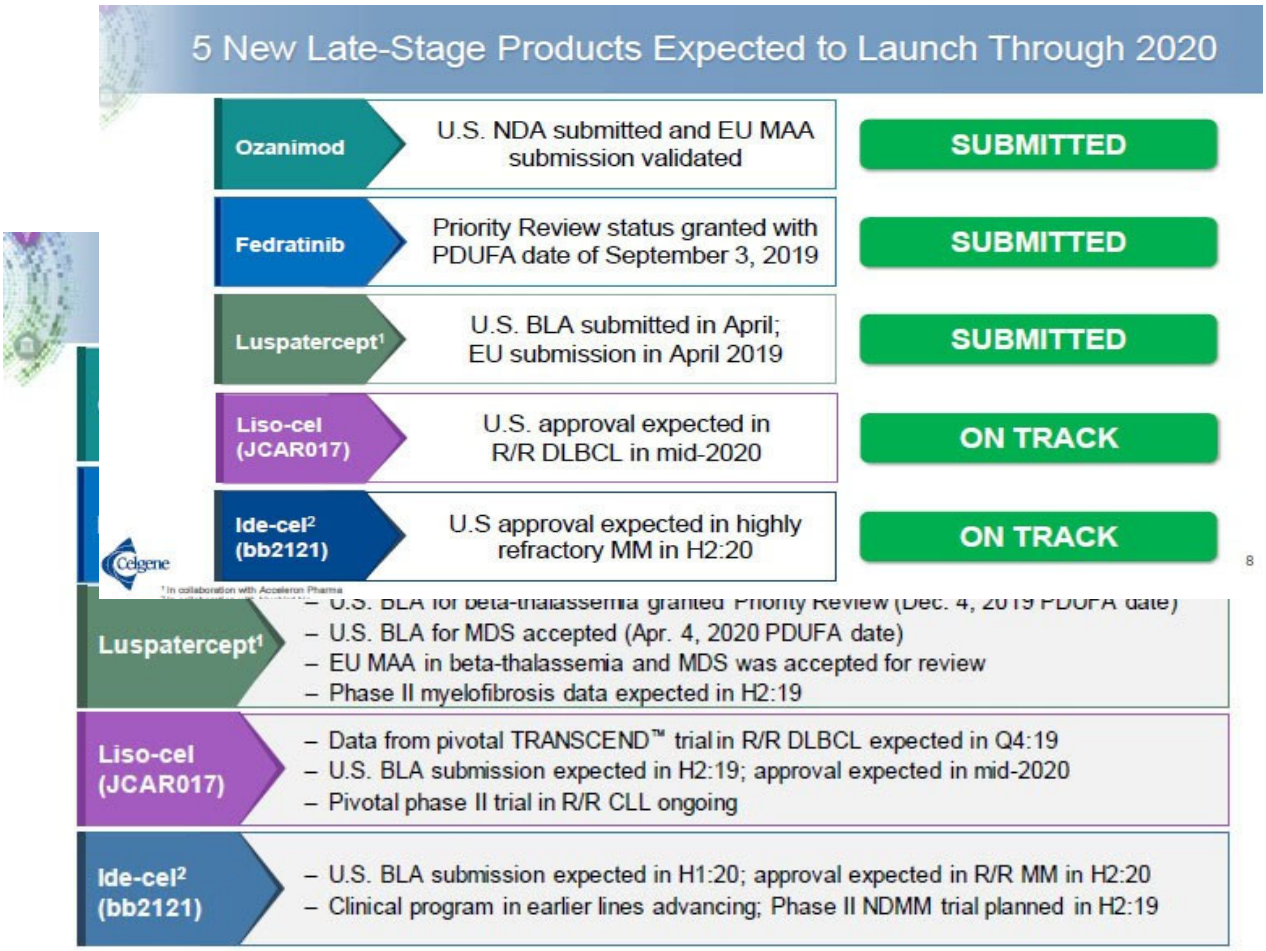
Lymphoma Late-Stage/Pivotal Programs

Patient Population	Relapsed or Refractory Indolent Lymphoma	Relapsed or Refractory B-cell NHL
Molecule	REVLIMID®	Liso-cel (lisocabtagene maraleucel; JCAR017)
Trial Name	MAGNIFY™ NHL-008	TRANSCEND-NHL-001
Phase	III	I
Target Enrollment	500	274
Design	Arm A: REVLIMID® (10-20mg, D1-21) + rituximab (375 mg/m² weekly for cycle 1 then D1 of cycles 3, 5,7,9 and 11 for 12 28-D cycles) followed by REVLIMID® (10mg, D1-21) + rituximab (375 mg/m² D1 of cycles 13,15,17,19,21,23,25,27 and 29 for 18 28-D cycles) followed by REVLIMID® (10mg, D1-21 until disease progression, 28 D cycle) Arm B: REVLIMID® (10-20mg, D1-21) + rituximab (375 mg/m² weekly for cycle 1 then D1 of cycles 3, 5,7,9 and 11 for 12 28-D cycles) followed by REVLIMID® (10mg, D1-21) + rituximab (375 mg/m² D1 of cycles 13,15,17,19,21,23,25,27 and 29 for 18 28-D cycles)	Arm A: JCAR017 single-dose schedule Arm B: JCAR017 2-dose schedule
Primary Endpoint	Progression Free Survival	Objective Response Rate; Safety
Status	Trial enrolling Data expected in 2020	Enrollment complete Submission expected for 2H:2019

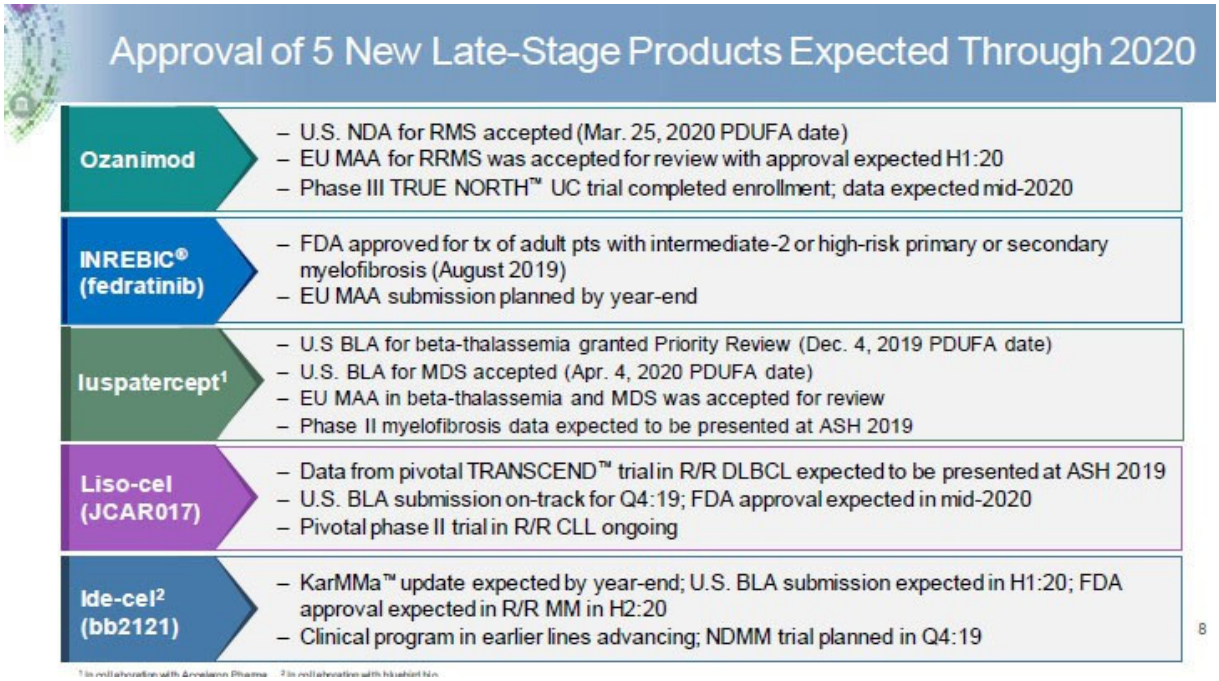
48

100. Similarly, in Celgene's First Quarter earnings presentation published April 25, 2019, it represented to investors that Liso-cel was "on track" and that U.S. approval was expected in "mid-2020." Several Bristol executives fielded questions from investors, including Defendant Caforio, Chief Financial Officer, Charles Bancroft, Chief Scientific Officer, Thomas Lynch, and Chief Commercial Officer, Christopher Boerner, during this presentation. Accordingly, analysts following the biotechnology industry noted that Liso-cel and the two other CVR therapies were likely to be approved ahead of their Milestones.

101. Celgene's Second Quarter 2019 earnings presentation published on July 30, 2019 again stated that Liso-cel approval was expected in mid-2020. Several Bristol executives fielded questions from investors, including Defendant Caforio, Head of Oncology Development, Fouad Namouni, and Chief Financial Officer, Charles Bancroft during this presentation. The presentation further explained that the data from the TRANSCEND trial for Liso-cel was expected in the Fourth Quarter of 2019:



102. In Celgene's Third Quarter earnings presentation published October 31, 2019, it represented that the BLA submission was "on track" for the Fourth Quarter and that "approval was expected in mid-2020":



103. Several Bristol executives fielded questions from investors, including Defendant Caforio, Chief Financial Officer, Charles Bancroft, Head of Worldwide Markets, Murdo Gordon, and Chief Scientific Officer, Francis Cuss during the presentation.

104. Simply put, prior to and following the announcement of the Merger, the submission of the BLA for Liso-cel was on track and FDA approval for Liso-cel was expected to occur well before the December 31, 2020 CVR Milestone.

C. Liso-Cel was of Critical Importance to Bristol's Acquisition of Celgene.

105. Given its revolutionary promise, Liso-cel was one of the core reasons for Bristol's decision to acquire Celgene, and determining the value of Liso-cel and Celgene's other pipeline drugs necessarily required extensive diligence by Bristol and the Individual 10(b) Defendants on the likelihood of their approval by the FDA, the status of the regulatory approval process and the timetable by which the drugs were likely to be approved.

106. In late December 2018, Bristol first proposed introducing a CVR component to the merger consideration for purposes of bridging a reduction in the upfront aggregate value per

Celgene share. Bristol's proposal was personally conveyed to Celgene's CEO, Mark Alles, by Defendant Caforio, who Bristol's Board of Directors ("Board") had previously authorized as its chief negotiator as to the terms of the CVR during a meeting on December 27, 2018. Bristol's initial proposal was for the CVR to provide a payout of up to $8 in the event that certain milestones were achieved following the closing. In the course of negotiations, members of Celgene's management proposed that the CVR provide a payout of up to $10, with $2 payable upon FDA approval of each of Celgene's five near-term, late-stage pipeline drugs. Celgene's Board noted that the terms of the CVR should be clear, tied to near-term events, and aligned with the strategy of the combined company.

107. Intense negotiations over the terms of the CVR Agreement ensued.

108. On December 27, 2018, members of Bristol management held a board teleconference for members of the BMS Board which included discussion of the introduction of a CVR component to the merger consideration for purposes of bridging a reduction in the upfront aggregate value per share. That same day, the CEOs of the two companies met to further discuss some form of CVR component as merger consideration.

109. On December 28, 2018, members of Celgene and Bristol- management discussed and negotiated the terms of a possible CVR, including the amount that could be payable under the CVR and the milestones that needed to be achieved prior to the making of such payments.

110. On December 29, 2018, the companies continued to negotiate the terms of the CVR.

111. On December 30, 2018, the BMS Board held a special meeting to further discuss the CVR payout, and Defendant Bristol CEO Caforio sent a letter to Celgene CEO Alles confirming the proposal discussed on December 29, 2018.

112. On December 30, 2018, Bristol sent Celgene its best and final offer as to the terms

of the CVR in a letter personally signed by Defendant Caforio. After some further negotiations, on January 2, 2019, Bristol and Celgene came to a final agreement on the price, catalyst events and dates for CVR payments. The $9.00 per CVR payment was contingent on each of the Milestones being achieved by December 31, 2020 for Liso-cel and Ozanimod, and March 31, 2021 for Ide-cel. If all three were approved by their respective Milestone dates, Bristol would owe the CVR holders $6.4 billion. If ***any*** Milestone were missed—even by a ***single day***—Bristol would owe the CVR holders ***nothing***.

113. From December 31, 2018 to January 2, 2019, Celgene, Bristol and their respective advisors continued to discuss and negotiate the open issues in the merger agreement and the CVR agreement.

114. Throughout the Merger negotiations, Defendant Caforio remained focused on the CVR terms, conveying Bristol was not willing to pay ***any*** amount under the CVR unless ***multiple*** milestones were ***all*** achieved before the specified milestone dates. Specifically, under Bristol's proposal, the CVR would pay out only if the FDA approved on or before December 31, 2020 the commercial manufacturing, marketing and sale of ***all*** of (i) Liso-cel, which treats diffuse large B-cell Non-Hodgkin's lymphoma; (ii) Ozanimod, which treats relapsing multiple sclerosis; and (iii) Ide-cel, which treats relapsed and refractory multiple myeloma (collectively, the "Milestone Therapies"). Defendant Caforio also stated that Bristol would only agree for the CVR to pay up to $9, not $10 as requested by Celgene.

115. Before the Merger announcement, all three Milestone Therapies were on the fast track for approval and well ahead of the pace needed to be approved by their Milestone deadlines, including Liso-cel. Throughout the Merger negotiations, Liso-cel continued to progress through FDA approvals under its designations as a Breakthrough Therapy and a Regenerative Medicine

Advanced Therapy. Clinical trials showed strong response rates in patients suffering from diffuse large B-cell Non-Hodgkin's lymphoma, and most patients did not experience the life-threatening side-effects associated with the two other FDA-approved therapies for this cancer. The FDA concluded the clinical trials were "well-controlled" and "demonstrated high response rates and durability of [complete response] rate."

116. In total, Bristol's Board held eight Board meetings to discuss the Merger.

117. In addition, the Science & Technology Committee, including Defendants Vousden, Emmens, Sato, and Arduini, provided further review of the agreement. On January 2, 2019, the Science & Technology Committee of the BMS Board convened to discuss in detail the results of the due diligence conducted with respect to Celgene, including, in particular, due diligence findings with respect to Celgene's products like Liso-cel and product pipeline opportunities.

118. Coloring all of this, at the time of Bristol's acquisition of Celgene, both companies had suffered struggling stock prices. Indeed, Bristol itself acknowledged its struggling valuation in its registration statement for the merger with Celgene, including noting CEO Defendant Caforio and Celgene CEO Alles met in October 2018 to discuss "the recent decline in the stock prices of biopharmaceutical companies, including both Bristol-Myers Squibb and Celgene"; Celgene Board discussed decline in stock price of both companies multiple times in December 2018; members of Bristol management reviewed the stock price declines of both companies in December 2018.

119. In late 2018, Bristol CEO Caforio was under pressure to turn things around at the Company. Since becoming Bristol's CEO on May 5, 2015, the Company's stock price had seriously underperformed the market. By the end of August 2018, Bristol's stock price was approximately 9.5% ***lower*** than when Caforio had taken over—at a time when the S&P 500 had risen over 35%. To make matters worse, Bristol's most important driver of growth, the cancer

therapy Opdivo, was falling behind its competitor Merck's competing therapy Keytruda. In the hopes of reviving Bristol's rapidly dwindling fortunes, Caforio "turn[ed] to dealmaking to revive the … company's fortunes."[8]

120. Given Liso-cel's pivotal role in the success of the Merger and the chances of Bristol paying an additional $6.4 billion to Celgene shareholders, and the importance of that merger and the CVR payoff to Bristol, the fact that Bristol's CEO was monitoring every significant Liso-cel development should not be a surprise.

D. Bristol Issues the Materially False and Misleading Registration Statement and Joint Proxy.

121. On January 2, 2019, Bristol and Celgene executed the Merger Agreement, which was signed by Defendant Caforio. For each outstanding Celgene share, Celgene shareholders received one share of Bristol common stock, $50.00 in cash and one CVR.

122. On February 20, 2019, Bristol, together with Celgene, filed a Registration Statement, which contained the relevant substance of the Joint Proxy. The Statement was signed by Giovanni Caforio; CFO Charles Bancroft; Senior Vice President and Corporate Controller Karen Santiago; and Directors Vicki Sato, Peter Arduini; Robert Bertolini; Matthew Emmens; Michael Grobstein; Alan Lacy; Dinesh Paliwal; Theodore Samuels; Gerald Storch; and Karen Vousden. On February 22, 2019, Bristol, together with Celgene, filed the Joint Proxy, soliciting votes on the proposed Merger. The Joint Proxy and Registration Statement stated that if shareholders approved the Merger, Celgene shareholders would receive one share of Bristol common stock, $50.00 in cash and one CVR for each outstanding share of Celgene stock they owned.

[8] Svea Herbst-Bayliss and Michael Erman, *Starboard joins opposition to Bristol-Myers' $74 billion Celgene deal*, Reuters (Feb. 28, 2019).

123. The Joint Proxy and Registration Statement also explained the agreement between Bristol and Celgene governing the CVRs. Specifically, it stated that "[e]ach holder of a CVR is entitled to receive $9.00 per CVR, which is referred to in this joint proxy statement/prospectus as the milestone payment, if the CVR milestone is achieved." Joint Proxy at 217. The Joint Proxy and Registration Statement provided the following completion dates for each of the Milestone Therapies in order for Celgene shareholders to obtain payment on the CVRs: "(i) the [Ide-cel] milestone has occurred on or prior to March 31, 2021; (ii) the [Liso-cel] milestone has occurred on or prior to December 31, 2020; and (iii) the Ozanimod milestone has occurred on or prior to December 31, 2020." *Id*.

124. Critically, the Joint Proxy and Registration Statement told Celgene shareholders that Bristol would engage in "***diligent efforts***" to achieve the CVR Milestone dates. Specifically, the Joint Proxy and Registration Statement informed shareholders that:

> Bristol Myers Squibb has agreed to use "***diligent efforts***" to achieve the CVR milestone. "Diligent efforts" means, with respect to [Ide-cel], [Liso-cel] or Ozanimod, efforts of a person or entity to carry out its obligations in a diligent manner using such effort and employing such resources normally used by such person or entity in the exercise of its reasonable business discretion relating to the research, development or commercialization of a product, that is of similar market potential at a similar stage in its development or product life, taking into account issues of market exclusivity (including patent coverage, regulatory and other exclusivity), safety and efficacy, product profile (including tolerability and convenience), the competitiveness of alternate products in the marketplace or under development, the launch or sales of one or more generic or biosimilar products, actual or likely pricing/reimbursement [Ide-cel], [Liso-cel] or Ozanimod, the likely timing of such product's entry into the market, the likelihood of regulatory approval of such product and applicable labeling, and the profitability of such product, and other relevant factors, including technical, commercial, legal, scientific, and/or medical factors, based on conditions then prevailing.

Id. at 219.

125. The Joint Proxy and Registration Statement also attached a Form CVR Agreement which disclosed the same to Celgene shareholders. *Id*. at B-2, B-22.

126. Relying upon the statements in the Joint Proxy, Bristol and Celgene shareholders approved the Merger on April 12, 2019.

E. Bristol Assumes Control of the Liso-cel Approval Process and Takes Intentional or Reckless Actions to Delay FDA Approval

1. Bristol Files A BLA For Liso-cel Lacking Basic Information About Liso-cel's Chemistry, Manufacturing, and Controls

127. Celgene submitted the first component of the Liso-cel BLA to the FDA on September 30, 2019, fifty-one days before the Merger became effective. A BLA is a request to the FDA to introduce a biologic product into interstate commerce. Its issuance requires a determination that the product, the manufacturing process, and the manufacturing facilities where the product is produced meet applicable requirements to ensure the continued safety, purity, and potency of the product. The BLA must include, among other things, clinical data demonstrating the safety and efficacy of the therapy, information concerning the manufacturing and controls for production, a detailed description of the manufacturing facility and the proposed product label. The FDA issues its approval once it has reviewed the BLA, conducted facility inspections, and concluded that the therapy is efficacious, safe, and appropriately labeled.

128. According to analysts of Guggenheim Partners, an investment and financial advisory firm, they were told the following in a meeting with Defendants Caforio and Bancroft (and CCO Chris Boerner) that occurred on November 7, 2019 or shortly before:

> Achievement of key milestones associated with the CELG pipeline CVR is on track; despite substantially high conviction in the components of the CVR, there are no plans to buy it back early. Mr. Bancroft noted that the tradable Contingent Value Right (CVR) is structured to pay CELG shareholders $9.00 in cash one-time if FDA approval is secured for all three products in ozanimod (by YE20), liso-cel/JCAR017 (by YE20) and bb2121 (by the end of 1Q21). Management emphasized several points, including (1) ***oversight of the CVR is a board-level responsibility*** and ***BMY is highly motivated to pay out the CVR*** because of the importance of the CELG pipeline to the company's future value; but (2) BMY has ***no plans to buy back the CVR early, either via open market purchases or a tender*** primarily because of the availability of asymmetric information available to BMY

> vs. the shareholders of the CELG CVR. As it relates to the CVR, we expect shares to trade purely on the events and probability that all three events are achieved in the allotted timeline.

129. Accordingly, analysts such as those from Guggenheim Partners continued to project at the time of the Merger's closing that all three drugs would be approved well ahead of their Milestone dates. As noted above, Defendants also told Guggenheim partners that Bristol would not buy CVRs early via open market purchases or a tender. That meant that even if Bristol could save money for its shareholders by purchasing CVRs on the open market for far less than the $9 a share it would owe if the Milestones were met, it would not do so. This is striking because, during the Class Period, the CVRs traded at prices between $0.61 and $4.76. While Bristol cited "asymmetric information" as its rationale for not doing so, that same asymmetric information did not stop Bristol from engaging in buybacks of its common stock during quarters ending on December 31, 2019, March 31, 2020, or December 31, 2020, and nine other quarters over the past five years. Bristol had an ulterior undisclosed motive for not purchasing CVRs in the open market: it knew the delaying tactics it employed would prevent FDA approval by the Milestone. Otherwise, it would have been a no brainer for Bristol to buy these CVRs at the lower prices and receive $9 after the Milestones were all met, thus ensuring a 100%-400% profit on such purchases.

130. Both the Merger and the CVR Agreement became effective on November 20, 2019. The remainder of the approval process for Liso-cel was then controlled by Bristol. The New Drug Application ("NDA") for Ozanimod, one of the three Milestone Therapies, had been submitted well before the Merger closed, and the FDA granted Ozanimod approval on March 26, 2020, shortly after the Merger closed. Thus, Bristol would need to pay CVR holders $6.4 billion under the CVR Agreement unless something happened to delay FDA approval for Liso-cel and/or Ide-cel, both of which were on the fast-track for approval well before their respective Milestone dates. Bristol then took affirmative steps by commission and omission to delay timely FDA approval. Its

scheme to defraud paid off, as it cheated others and saved itself $6.4 billion.

131. Bristol's actions to delay the approval of Liso-cel began almost immediately with its decision to delay Liso-cel's Chemistry, Manufacturing and Controls ("CMS") data, ***the most important section of the BLA,*** until December 18, 2019. According to the FDA Biologics Expert—based on experience at the FDA with similar BLAs—the CMC should have been prioritized, and submitting key parts of the CMC section of the BLA 79 days (from September 30, 2019 to December 18, 2019) after the rest of the application was submitted was an unusually long period of time. Under FDA policy, the FDA then had only sixty days to conduct an initial review to determine whether the application was complete and whether to grant "Priority Review" for Liso-cel.

132. The FDA reserves Priority Review for therapies that are significant improvements to the safety or efficacy of the treatment, diagnosis, or prevention of a serious condition. A "Priority Review" designation provides a substantial benefit to the manufacturer as it reduces the time of the review process. The FDA commits to try to render a decision on all BLAs by a set date. For drugs with Priority Review, that date is six months after the initial review—four months shorter than its typical review time. The FDA strives to approve or deny BLAs and NDAs by its stated date at least 90% of the time. In reality, the FDA does even better. For the 155 BLAs and New Molecular Entity Drug Applications (which are reviewed under the same program) that were granted Priority Review in fiscal years 2014 through 2018, the FDA made a decision by its goal date in all but three instances, which is ***98%*** of the time. For fiscal years 2016 to 2018, the FDA approved those applications by its goal date ***100%*** of the time.

133. According to the FDA Biologics Expert, to conduct an apples-to-apples comparison, one should consider ***all parenteral cell/gene therapy biologics (Advanced Therapies)***

approved by FDA/CBER/Office of Tissues and Advanced Therapies ("OTAT") at the time Liso-cel was approved, and during the pandemic, except for tissue type products (non-parenteral), and cord blood (minimally manipulated) as these are not Advanced Therapies, and except for those manufactured outside of the U.S. where FDA/Team Biologics was not inspecting at the time. After excluding those biologics, one is left with biologics that are directly comparable to Liso-cel, because they all undergo identical approval processes within CBER and OTAT and were inspected by Team Biologics in-person and CBER virtually at the time, like Liso-cel, a parenteral product.

134. The FDA completed its initial review of the Liso-cel BLA on February 13, 2020, and granted it Priority Review. This meant that, despite Bristol's delay in submitting the most important part of the BLA (*i.e.*, Liso-cel's CMC data), the FDA aimed to review Liso-cel by August 17, 2020—***four and a half months before*** the December 31, 2020 Liso-cel Milestone date. As one analyst noted optimistically, this PDUFA date was "another positive step" for CVR holders, because it "could even allow for a three-month delay (which we do not expect)." As the COVID-19 pandemic began, another analyst concurred that the early PDUFA date would help Bristol meet the CVR milestone, writing that "the CVR as a whole can withstand a 3- to 4-month delay, if one were to occur," and assuring investors that Liso-cel in particular had a "4.5 month buffer." That is, ***even accounting for substantial delays, including those prompted by COVID-19***, all indications were that FDA approval of Liso-cel would meet the CVR deadline. Indeed, retrospective analyses of Bristol's failure to timely receive FDA approval for Liso-cel independently found that failure could not "likely" be blamed on the pandemic.[9]

135. But even a 4.5-month buffer is not sufficient if the Company is deliberately or

[9] *Delayed JCAR017 Approval Likely Was Not Just Due to COVID-19 per Recently Posted FDA Memos*, Mizuho Securities USA LLC (April 7, 2021).

recklessly slow-walking the approval process. Soon after completing its initial review of the Liso-cel BLA, the FDA found significant additional omissions in Bristol's BLA. As revealed in an FDA memorandum released publicly in 2021, Bristol's CMC submission omitted basic data detailing (i) the tests used to ensure that Liso-cel is safe and efficacious, referred to as assays, and (ii) the studies that assess whether those assays worked as they were supposed to, referred to as validation. Such data are usually rigorously compiled over the course of developing a biologic and are routinely included in BLAs. As Bristol knew or should have known, they are fundamental components of a BLA, without which the FDA cannot make an informed decision, and thus will not make any decision, about approval. According to the FDA Biologics Expert, a company diligently seeking approval of a biologic would not have omitted such assays from its BLA submission and would have understood that omitting such assays could significantly delay FDA approval.

136. It is implausible that one competent regulatory affair specialist would have accidentally omitted this critical data from the FDA submission and inconceivable that no members of a team of upwards of ten regulatory specialists would have noticed the omission of this basic, favorable data.

137. Moreover, the degree to which Bristol's Chief Medical Officer of Global Drug Development, Defendant Hirawat, spoke about the progress of Liso-cel's approval throughout 2020 underscores the degree to which Bristol's involvement in Liso-cel's approval ran from the bottom to the top of the Company. Hirawat presented at conferences on the projected approval dates for Liso-cel and he spoke on investor webcasts about the drug's approval being "on track". On earnings calls, Hirawat provided updates on the status of Liso-cel's application, and he presented to investors the details of Liso-cel's failed BLA submission. Hirawat provided details at biopharma conferences the state of Celgene's facilities and spoke on Zoom panels about

Bristol's "continuous dialogue with the FDA." Hirawat also gave interviews in which he spoke about Liso-cel's being "on track" to meet its approval goal and announced the completion of inspections at some facilities.

138. On March 23, 2020, the FDA submitted an information request to Bristol seeking the missing data on assays and validation. More than three weeks later, Bristol finally amended the CMC section of the BLA to provide the missing information on April 15, 2020. According to the FDA Biologics Expert, this 23-day delay in providing the missing information to the FDA was also "highly unusual," because a company at this stage of the BLA process would almost certainly have already had the necessary data and be able to ***immediately*** submit it.

139. Within weeks, the FDA concluded that the new information Bristol provided in the amendment was so substantial that its submission constituted a Major Amendment to the Liso-cel BLA. A Major Amendment would only be triggered by substantial information that changed the nature of some component of the BLA. Major Amendments are so rare that Confidential Witness ("CW") #1, who has years of experience in the industry including involvement in the FDA approval of approximately twelve to thirteen different drugs, had never experienced a Major Amendment before and was deeply disappointed when the Major Amendment was announced. CW #1 stated, "I perceived [the Major Amendment] as a major blunder." Given Bristol's full understanding that it was on a specific timeline for gaining FDA approval, its failure to provide an adequate initial submission is shocking. According to the FDA Biologics Expert, the FDA typically tries to avoid issuing a Major Amendment Acknowledgment Form because it often results in missing the PDUFA date. Under Standard Operating Policy and Procedure 8402, the FDA only does so if there is a "substantial amount" of new data or new manufacturing or facility information, or if there is a new analysis of clinical studies not previously submitted to the FDA. The FDA is

largely successful in avoiding the necessity of this designation and does so only in the rarest of situations. This is because a Major Amendment automatically extends the review of the therapy by three months. A Major Amendment for a cancer therapy designated as both a Breakthrough Therapy and a Regenerative Medicine Advanced Therapy and selected for Priority Review is the rarest of rare occurrences, since the purpose of such designations is to ensure the FDA is deeply involved in the therapy's development.

140. Liso-cel's "major amendment" designation automatically triggered the three-month extension of the FDA's target review date—from August 17, 2020, to November 16, 2020, only six weeks before the December 31, 2020, Liso-cel Milestone date. Had Bristol satisfied its stated contractual obligation to exercise "diligent efforts" to achieve the Liso-cel Milestone, there would not have been a Major Amendment or the accompanying delay in FDA approval. Nonetheless, even after the announcement of the three-month delay, financial analysts continued to predict based on Bristol's representations that approval of Liso-cel before the end of 2020 was more likely than not.

2. Bristol Further Delays FDA Approval by Failing to Adequately Prepare the Liso-cel Manufacturing Facilities

141. Bristol also caused critical delays during the next step of the FDA's review of Liso-cel's BLA–the Pre-License Inspection of the Liso-cel manufacturing facilities. A Pre-License Inspection aims to ensure that the facilities used to manufacture a therapy comply with basic FDA safety regulations and requirements. The two facilities to be inspected were the Juno Facility in Bothell, Washington and the Lonza Facility in Houston, Texas. Bristol is responsible for ensuring that both facilities comply with FDA regulations, including through monitoring and instructing its contract vendor at the Lonza Facility concerning FDA compliance.

142. Bristol knew that: (i) the Pre-License Inspections were critical to timely FDA

approval of the Liso-cel BLA; and (ii) the FDA had already rescheduled the June 2020 Pre-License Inspections for Liso-cel's manufacturing facilities after the major amendment pushed the Liso-cel review back three months. Thus, the rescheduled inspections had the possibility of delaying Liso-cel's approval beyond the Liso-cel Milestone if they did not go smoothly.

143. However, because the FDA understood the life-saving importance of Liso-cel, it rescheduled the Pre-License Inspection for later in 2020. The FDA provides advance notice to manufacturers prior to conducting Pre-License Inspections to give manufacturers the opportunity to fix problems before the inspection and streamline the Pre-License Inspection process. Thus, Bristol was well aware of the upcoming Pre-License Inspections and had ample time to prepare both the Juno and Lonza Facilities. The delay in scheduling the inspections caused by the Major Amendment provided Bristol with even more time to ensure the facilities were adequately prepared.

144. Shortly after Bristol acquired Celgene, it described Liso-cel's manufacturing facilities in public presentations as "launch ready." In reality, according to CW #2, a former Manager of Audit and Inspections at the Lonza facility, Bristol and Lonza had concluded that there was a lot of work left to be done after their mock pre-approval inspection in the fall of 2019 and that Bristol was concerned that Lonza would ***not*** be prepared in time for the FDA inspection. Yet, Bristol failed to take the necessary steps to ensure it would be ready for the FDA inspection. After a year under Bristol's control, those facilities fell far short on basic safety and regulatory requirements. Despite the FDA's inspection notice and Bristol's opportunity to get ready and address any deficiencies, both facilities were left woefully unprepared.

145. The Juno Facility inspection occurred from October 7, 2020, to October 16, 2020. Following that inspection, the FDA issued a Form 483, which documents "significant" issues

identified during an inspection that may violate FDA regulations because they pose a risk that therapies could be adulterated and harm patients. These observations must be addressed to the FDA's satisfaction before approval is granted.

146. The FDA observed at the Juno facility that Bristol failed to thoroughly review any unexplained discrepancy. For instance, the facility failed to establish the reliability of the Certificates of Analysis from the vendor supplying certain starting materials. Bristol's failure to meet this basic requirement of the Current Good Manufacturing Practices, the minimum requirements specified by FDA regulations for manufacturing a drug product, was either intentional and/or reckless. According to the FDA Biologics Expert, this observation reflects a failure of Bristol to investigate important deviations in its manufacturing process and elsewhere – a central tenet of quality assurance. As the first observation in the Form 483, this was the single most important failure of the inspection.

147. The FDA also observed that the Standard Operating Procedures at the Juno facility were improperly written, specifically, SOP-000512 regarding inspection of materials failed to differentiate between the visual inspection for raw materials and the visual inspection for final products. According to the FDA Biologics Expert, this is an error that should have been avoided and that an experienced company like Bristol with licensed biologic products should not have made.

148. The FDA also observed deficiencies in the procedures the Juno facility should have had in place to prevent microbiological contamination of sterile drug product, including with the aseptic practices of Juno facility personnel. Proper procedures for aseptic and sterilization processes are required by 21 CFR 211.113. The FDA specifically observed an individual sanitizing their gloves just before sampling them for environmental monitoring plates. The FDA's guidance

specifically states that "[s]anitizing gloves just prior to sampling is inappropriate because it can prevent recovery of microorganisms that were present during an aseptic manipulation." According to the FDA Biologics Expert, anyone who does aseptic processing knows this and, as such, it was an error that was easily avoidable. The FDA also noted that an operator was observed not following Standard Operating Procedure 000567 during the aseptic monitoring, which the FDA Biologics Expert stated would either be due to a mistake or poor training.

149. Finally, the FDA also observed poor controls in the analytical lab at Juno Therapeutics. According to the FDA Biologics Expert, this was an unusual and avoidable error that any company with licensed biological products should not have committed.

150. As Bristol is one of the world's largest pharmaceutical companies and has brought many of the therapies to market, it knew or should have known these deficiencies were unacceptable in advance of the FDA's inspection and fixed the issues. According to the FDA Biologics Expert, numerous issues identified in the Form 483 should have been identified during routine mock pre-approval inspections or other inspection preparation, and could have been easily addressed prior to inspection given the considerable time Bristol had to prepare for the FDA audit. Yet, Bristol's overt failure to comport with basic FDA standards for safe and reliable manufacturing further delayed the FDA's approval of Liso-cel.

151. Bristol then caused further delay of approval in how it responded to the Form 483. First, it took longer than necessary to respond. After receiving a Form 483 detailing deficiencies for the Juno inspection that concluded October 16, 2020, Bristol took twenty-one calendar—or fifteen business days, the maximum allowed for a Form 483 response under FDA policy—to respond to the Form 483 on November 6, 2020. According to the FDA Biologics expert, Bristol's response to the Juno Form 483 could have easily been completed—especially given the size of the

approval team—in ten calendar days. Second, Bristol's response to the Juno Form 483 was inadequate. According to the FDA's comments on Bristol's Form 483 response, Bristol stated it would take actions "to further enhance" its "processes and controls and improve the overall effectiveness of [its] operations and quality system." According to the FDA Biologics Expert, it would have been clear to Bristol that its Form 483 response was obviously inadequate, as there are clear industry standards for how to respond to the particular issues raised in the Form 483. Specifically, in responding, a company should, among other things, acknowledge and demonstrate that it understands the significance of each observation or deficiency in the Form 483, describe in detail what corrections the company will make to address each observation or deficiency, and explain when the corrections will be made using realistic time frames.

152. Thus, according to the FDA Biologics Expert, Bristol would have known that its response would cause further delay by requiring supplementation. Indeed, that is what happened. The FDA found that Bristol's Form 483 response included "unclear and questionable points" and, therefore, it required Bristol to supplement its response. Bristol did not complete its supplemental Juno Facility Form 483 response until December 18, 2020, over ***two months*** after the FDA inspection, a ***month*** after the FDA's target review date, and ***less than two weeks*** before the Liso-cel Milestone date. For an industry titan like Bristol, according to the FDA Biologics Expert, a failure to adequately respond to a Form 483 is rare—and a two-month gap between the inspection and the final Form 483 response is ***unheard of***. The FDA could not complete its review of the Liso-cel BLA until this response was complete. Had Bristol actually used diligent efforts, such further delay would have been avoided.

153. Remarkably, Bristol repeated many of the issues from the Juno Facility inspection during the inspection of the Lonza Facility. Instead of sending a team of experienced senior

consultants with relevant experience to the Lonza Facility to prepare it for its inspection, they deliberately sent Christopher Knecht, a young employee with no experience working on an FDA pre-approval inspection (let alone experience overseeing preparations for cell therapy or viral manufacturing inspection), to handle the inspection. This is particularly shocking given the fact that the Lonza facility had never undergone an FDA inspection before. According to the FDA Biologics Expert, sending an inexperienced staff member to prepare a critical facility for an FDA inspection for a high priority biologic would be a "shocking" recipe for failure and contrary to standard industry practice. According to the FDA Biologics Expert, Bristol should have done the exact opposite: send a team of the company's most senior employees with inspection-preparation experience.

154. Following the FDA's inspection of the Lonza Facility from December 3, 2020, to December 10, 2020, it issued a Form 483 that identified a litany of errors. Many of these errors overlapped with similar problems identified during the Juno Facility inspection. For example, during both inspections, the FDA identified deficiencies in the inspection of raw materials and inadequate microbial contamination controls. Following the Juno Facility inspection, Bristol could have—and should have—ensured that it corrected these issues before the Lonza Facility inspection. It simply chose not to. According to the FDA Biologics Expert, not correcting certain of these known issues prior to an FDA inspection would be highly unusual and contrary to standard industry practice.

155. The other issues the FDA observed at the Lonza Facility, while different from those at the Juno Facility, reflected the opposite of "diligent efforts" to ensure Liso-cel's timely approval.

156. The FDA made four observations in the 483 it issued for the Lonza facility, including examples of each observation:

157. The FDA's first observation was that "physical and electronic control of material storage areas is not adequate." Proper material storage is a basic component of Current Good Manufacturing Practices. Relevant to the FDA's exemplars, 21 CFR 211.42, 211.130, 211.130, and 211.142 require that there is adequate space, systems, and labeling in place in order to permit the proper storage and management of material and to prevent mix-ups.

158. Bristol knew of the issues with material inventory and storage at Lonza well-before the December 2020 FDA inspection. The FDA Biologics Expert confirms that proper material management in order to avoid mix-ups is Current Good Manufacturing Practices, and as such a contract manufacturing company like Lonza and a biopharmaceutical company like Bristol knew or should have known the state of material storage and handling at Lonza was unacceptable. The FDA Biologics Expert further confirms that issues with regard to the physical and electronic control of material storage areas would or should have been identified by BMS in a properly conducted mock audit in preparation for the FDA inspection, such as the mock audit CW #2 attested Bristol conducted in the fall of 2019 at the Lonza facility. Further, multiple CWs have attested that Bristol, in fact, knew of the issues at Lonza. CW #2, who was involved with compliance at the Lonza facility and had direct contact with Lonza's clients including Bristol and Juno, stated that after Bristol's fall 2019 mock-audit, Bristol and Lonza concluded that "there's a lot of work that needs to be done" and even formed a task force to purportedly address the problems at the Facility. CW #2 had the impression Bristol was "scared [Lonza] [was]n't going to make it"; a Bristol employee working with Lonza berated and screamed at CW #2, complaining that things at Lonza were not going well despite how much money Bristol was spending at Lonza. CW #3 stated that ***Bristol was "absolutely" aware*** of the issues with the management of Bristol's materials. CW #3 noted that Bristol had calls two to three times per week with different teams at

Lonza, and CW #2 noted that someone from Juno or Bristol was regularly at the Lonza facility through at least January 2020. CW #3 also stated that Bristol was informed it had unrealistic expectations given the resources it had provided for how quickly Lonza could do the work it requested. For instance, CW #3 stated that Lonza employees would provide Bristol with specific examples of what parts of their timeline were unrealistic and with specific estimations of how long something would realistically take, but Bristol refused to adapt to the reality of the situation. CW #4, CW #5, and CW #6, who all worked in Lonza's warehouse and confronted these issues on a regular basis in their day-to-day operations, each confirmed that the issues with Lonza's management and storage of materials was visible to anyone who entered the facility. CW #5, a Lonza warehouse employee with prior experience in a pharmaceutical warehouse, and CW #6, a warehouse employee with prior experience in a chemical warehouse, described the state of the warehouse as visibly shocking as of November 2020, with materials sitting in aisle ways in front of the racks and stored in trailers backed up to the loading docks. According to CW #4, a Logistics Specialist at Lonza, "it was a known fact" that Lonza's warehouse did not have sufficient capacity to properly support its operations and that the storage space dedicated to Bristol's manufacturing was insufficient; this insufficient capacity was related to many of the issues identified in the Form 483 as overcrowding in the warehouse would lead to deficiencies in properly segregating materials. CW #4 stated that the issues in Lonza's warehouse existed as far back as January 2019, and were still not being addressed by the time CW #4 left Lonza in October of 2020.

159. Indeed, appearing on a November 26, 2019, panel to discuss cell therapy manufacturing, Bristol's own employee, Snehal Patel, the Vice President of the Global Manufacturing Network and Site Head at the Juno facility in Bothell, acknowledged that the Company was suffering from ***"self-inflicted wounds."*** Shockingly, during that same appearance,

Patel noted that the Company had experienced an "aha!" moment when it determined that "Grade B really meant Grade B" with respect to FDA approval. This comment—which made clear that Juno required tremendous assistance from Celgene and, subsequently, Bristol in understanding how exacting FDA approval protocols could be—put Bristol on notice as to the potential challenges with FDA approval from early on. Patel, the Site Head, was an integral person in the preparation and inspection of the Juno facility, listed as one of the "top officials" in the FDA Juno inspection report. He was present for the opening meeting with the FDA, and noted as "[a]ccountable for building, leading, and optimizing the operations of the global cell therapy manufacturing network."

160. The FDA provided a number of examples of Bristol's improper storage of materials:

a. First, the FDA noted that there were not separate storage areas for different materials in order to avoid mix-up; for instance, materials intended for use within the United States were stored in the same bin within the same freezer that stored materials intended for foreign markets, as well as materials that had been rejected by quality control. These problems were well-known. For example, Bristol failed to ensure that it had allotted to its production adequate space in the Lonza warehouse to have its materials stored properly. CW #4 stated that while Bristol had a certain amount of storage space dedicated to their product in the Lonza facility, it was not enough. According to CW #4, Bristol needed two or three times more storage space than they had to store product adequately. CW #4 also noted that these storage issues were longstanding and had existed since at least January 2019. Further, Bristol failed to ensure Lonza understood the requirements of proper

storage of its materials. CW #7, for example, described not having been told about any requirement to store product destined for U.S. distribution separate from product destined for foreign distribution. The FDA Biologics expert confirmed that this was a "glaring" violation of basic Current Good Manufacturing Practice to avoid mix-ups.

b. Second, the FDA noted that materials were labeled in a manner that made mix-ups likely. Again, this was a well-known problem. For example, CW #6 noted that the "RELEASED" labels were confusing and unclear, an issue Lonza was aware of and knew needed to be remedied. The FDA Biologics expert confirmed that this was a "glaring" violation of basic Current Good Manufacturing Practice to avoid mix-ups.

c. Third, the FDA noted that Freezer bins containing materials were poorly maintained and organized. Bristol again was aware of this issue. For example, while working in the cold storage room in the late fall of 2020, CW #5 stated that the freezer bins were poorly organized and contained materials that had previously been lost; for instance, CW #5 once came across vials of medicine for which CW #5's colleagues had been looking for months. CW #3 similarly noted that "things were piling on top of each other" due to the overcrowding in the warehouse. The FDA Biologics expert confirmed that this was a "glaring" violation of basic Current Good Manufacturing Practice to avoid mix-ups.

d. Fourth, the FDA noted that materials were stored on a metal rack that did not have a location in the SAP material inventory management software and that the materials on the rack were not labeled to indicate the status of the materials. Bristol

had significant advance notice that Lonza's warehouse had issues with its SAP system. CW #3 stated that the inventory system did not always indicate if a material had been used by the manufacturing facility, discarded or destroyed; and in other instances, material physically in the warehouse was not referenced in the inventory system. CW #3 indicated that these inventory issues existed at least six months prior to the FDA audit and that Bristol was "absolutely" aware of the issues with the inventory. The FDA Biologics expert confirmed that this was a "glaring" violation of basic Current Good Manufacturing Practice. The failure to maintain electronic and physical separations of human-use and non-human-use substances was a "shocking" failure that easily could have resulted in a full re-inspection.

e. Fifth, the FDA noted that a freezer that contained quarantined material was not properly locked. This too was a known, existing problem. CW #5, for example, confirmed that freezers were not always locked. Further, CW #5 noted Lonza did not take seriously the need to secure certain materials with locks. CW #5 stated that each freezer had a specific key, and the keys were kept in a lockbox in the warehouse; all of the employees knew about its location; a 4-digit code was used to open the lockbox; but it was commonly known that an employee had written the code in pen on the bottom of the lockbox. The FDA Biologics expert confirmed that this failure to lock freezers containing quarantined materials violates basic Current Good Manufacturing Practices.

f. Sixth, the FDA noted that Bristol failed to timely ensure its expired materials were properly discarded. This was a longstanding problem at Lonza and was the responsibility of Bristol to handle. According to CW #7, when materials expired at

the Lonza facility, Lonza employees had to obtain Bristol's approval before they could discard the expired materials. Accordingly, Lonza could not have resolved this issue without Bristol's involvement. Further, Bristol failed to ensure it had adequate space allotted to its materials to ensure proper inventory could be taken of what it had in the warehouse and that Lonza had sufficient staff to properly inventory the material. CW #3 stated that "there was too much material" and there was not sufficient staff in the warehouse in order to properly dispose of expired material. These issues existed well before the FDA audit. CW #4 stated that the issues with insufficient space existed at Lonza since at least January 2019, and CW #3 stated that the issues with the inventory control systems existed when CW #3 arrived at the facility in the summer of 2019. CW #3 stated that the inventory system did not always indicate if a material had been used by the manufacturing facility, discarded or destroyed; and in other instances, material might have been physically in the warehouse, but there was no reference to the material in the inventory system or vice versa. These issues, CW #3 stated, "went on for too long" at Lonza, and Bristol was "absolutely" aware of the problem. The FDA Biologics expert confirmed that this violates basic Current Good Manufacturing Practices.

161. The FDA's second observation was that certain material was not properly tested in order to confirm the identity of the material prior to release for manufacturing. Verifying the identity of a product is a basic Current Good Manufacturing Practice required by 21 CFR 211.84(d)(1). According to the FDA Biologics Expert, this violation reflected a basic failure to properly communicate between Bristol and Lonza. Further, the FDA Biologics Expert confirms that issues regarding the physical and electronic control of material storage areas would or should

have been identified by Bristol in a properly conducted mock audit in preparation for the FDA inspection, such as the mock-audit CW #2 attested Bristol conducted in the fall of 2019 at the Lonza facility.

162. The FDA's third observation was that written procedures were not uniformly followed. In particular, those regarding visual inspection and environmental monitoring. Following written procedures is a basic Current Good Manufacturing Practice. The FDA Biologics Expert confirms that compliance with written procedures is a basic requirement that Bristol, as a sophisticated and experienced pharmaceutical company, would have or should have known and that this error was avoidable. However, Bristol failed to ensure that Lonza employees understood and followed written procedures. For example, CW #8, a manufacturing technician at Lonza, stated that individuals on the Environmental Monitoring Team expressed to him that they did not think they had been sufficiently trained to do their jobs and that the Environmental Monitoring Team was insufficiently staffed, a concern they also conveyed to their managers.

163. The final FDA observation was that there were inadequate microbial contamination controls. The establishment of appropriate microbial contamination controls is a basic Current Good Manufacturing Practice. The FDA Biologics Expert confirms that such controls are a basic requirement that Bristol, as a sophisticated and experienced pharmaceutical company, would have known and had the authority to take the necessary steps to avoid. As discussed above, however, the Environmental Monitoring Team at Lonza was insufficiently trained and staffed, so did not appropriately understand or follow such controls.

164. Notably, according to the FDA Biologics Expert, many of the issues identified in the Form 483 should have been identified by Bristol during routine mock pre-approval inspections or other inspection preparation and could have been easily addressed and fixed prior to the FDA

audit given the considerable time Bristol had to prepare. Indeed, Bristol Vice President, Site Head at the Juno facility, Snehal Patel, had publicly confirmed that the Company was engaged in the regular practice of conducting mock pre-approval inspections. This fact makes Bristol's failure to have either of these facilities prepared for inspection all the more inexplicable, unless it was deliberate as CW #8, CW #5, and CW #6, all former Lonza employees, reported that the issues at Lonza were not improving or even being addressed by the fall of 2020.

165. Moreover, according to the FDA Biologics Expert, these failures marked the final nail in the coffin for the Liso-cel CVR: with inspection-related issues still outstanding at the eleventh hour of December 18, 2020, timely FDA approval of Liso-cel had been rendered "virtually impossible." According to CW #11, a senior quality assurance specialist at Juno Therapeutics/Bristol Myers during the relevant time, their vacation for mid-December 2020 was approved, an action they claim Bristol would not have taken if there were any chance Liso-cel would be approved by the Milestone date.

166. Bristol first responded to the Form 483 for the Lonza Facility on December 18, 2020, the same day it submitted its supplemental response to the Juno Facility Form 483. This response, like the first response to the Juno Facility Form 483, was woefully deficient and required Bristol to submit additional information. Bristol did so on December 23, 2020—again, ***just days*** before the Liso-cel Milestone and in the middle of the winter holidays. According to the FDA Biologics Expert, it is rare and contrary to standard industry practice for an initial response to a Form 483 to be insufficient—and even rarer and less excusable for a second response to also be insufficient.

F. Bristol Executives, Including Individual Defendants, Knew of or Recklessly Disregarded The Repeated Missteps in the Liso-Cel Approval Process

1. Bristol Executives' Repeated Commentary on the FDA Approval Process Demonstrate That They Were Intimately Aware of the Failures in Connection with Liso-Cell

167. Bristol's executives repeatedly provided assurance and commentary on the state of Liso-cel's FDA approval. In the weeks leading up to the Merger and the CVR Agreement's becoming effective on November 20, 2019, Defendants emphasized to investors that approval of Liso-cel and the other CVR drugs was on track and that executives and Board members were committed to achieving timely approval of the drugs before their respective Milestones. After the acquisition, Bristol publicly described Liso-cel's manufacturing facilities as "launch ready." Vice Bothell Site Head Snehal Patel assured the public that Bristol was conducting mock pre-approval inspections of its Liso-cel sites. Late in 2020, Bristol represented to investors that FDA approval for Liso-cel was delayed due to pandemic-induced issues.

168. Defendant Caforio, specifically, made the following statements evidencing his close monitoring of the FDA approval process for the Milestone Drugs, including Liso-cel:

a. On the February 6, 2020 earnings call stated that "we continue to advance our regulatory filings for liso-cel, ide-cel and CC486."

b. On June 25, 2020, during a presentation as part of Bristol's Investor Day Series, Defendant Caforio stated "we feel really good about where we are from a regulatory perspective. So that applies to products that may be included in the CVR as well as the rest of the portfolio."

c. On an August 6, 2020 earnings call, Defendant Caforio stated that "in the very near term, we are looking forward to the U.S. PDUFA dates for CC-486 in September, Liso-cel in November."

d. On, September 17, 2020, during a presentation at Morgan Stanley's 18th Annual Global Healthcare Conference, Defendant Caforio responded to a question about

the timing of the Liso-cel facilities inspections by blaming the COVID-19 pandemic for jeopardizing timely approval by the FDA by delaying site inspections.

e. On September 30, 2020, Defendant Caforio made a statement before the Committee on Oversight and Reform of the U.S. House of Representatives where he said "the FDA has accepted our submissions for liso-cel and ide-cel this year, and granted priority review for both."

f. On the November 5, 2020 earnings call, Defendant Caforio responded to a question requesting an update on the FDA's Liso-cel and Ide-cel review by saying "with respect to liso-cel. As always obviously we will update you as our discussion with the regulatory authorities progress."

169. Throughout all of his assurances, Caforio was aware that managing to miss the Milestone date by even a single day for a single drug would save his Company billions of dollars. As he explained on November 18, 2020—just a few weeks before the deadline transpired—Caforio underscored for the public that "[t]here [was] not a force majeure in the CVR" and Bristol would not alter the CVR deadline.[10] At the same time, Caforio continued to falsely assure the public that Bristol was "working with the FDA," and "ready" "for any type of inspection." Indeed, if Bristol intended to operate in good faith with respect to its investors, and the delay was solely due to COVID-19, there is no reason Bristol could not have simply pushed its CVR deadline to account for the pandemic.

170. Defendant Hirawat was the Chief Medical Officer, Global Drug Development and reported regularly to Defendant CEO Caforio. His close supervision, and monitoring of, the

[10] John Carroll, *Renegotiate the $6B CVR deal Bristol Myers made for the Celgene buyout? Caforio says that's not happening*, EndPoints News (Nov. 18, 2020).

progress of Liso-cel and the other Milestone Drugs in the FDA regulatory process was part of his job and evidenced by his public statements on the matter as well:

a. On December 8, 2019, Defendant Hirawat presented at the American Society of Hematology conference and reiterated plans to file liso-cel for approval by the end of the year.

b. On December 9, 2019, Defendant Hirawat stated during an investor webcast to discuss highlights from the American Society of Hematology conference, "as we had communicated right at the beginning of the year for liso-cel submission, we are on track for submitting liso-cel by the end of this year."

c. On May 7, 2020, during an earnings call, Defendant Hirawat stated with respect "liso-cel, as you know, that we had submitted the application with comprehensive datasets at the end of last year. And the FDA accepted the Application for liso-cel and granted a priority review in February of this year. Now, it is typical for the FDA to request additional information as they continue their review process and ask to the company supplied information in response to several requests that the FDA has made. FDA has decided that the information they have received constitute a major amendment. And that's why the PDUFA date has been extended by three months to the 16th of November now."

d. On May 19, 2020, during a presentation at the UBS Virtual Global Healthcare Conference, Defendant Hirawat stated that "we look towards hopefully approval of liso-cel towards the end of this year and we continue to go forward."

e. On June 25, 2020, during a presentation as part of Bristol's Investor Day Series, Defendant Hirawat described in detail the deficiencies in the CFC portion of the

BLA for Liso-cel and ide-cel: "liso-cel has a best-in-class CD19 targeting profile with a high affinity and differentiated safety. We look forward to bring this call to patients soon because we have a PDUFA date of November 16 this year… For liso-cel, there are specific questions that were asked that required for us to provide more data that were considered to be large enough that the agency needed to do the scientific review of it and extended the time line through a major amendment. And the third case for ide-cel, basically, there was a lot more data that was required instead of the summary reports we had included in the file. So there are, I think, different issues."

f. On September 8, 2020, during a presentation at Citibank's 15th Annual BioPharma Conference, Defendant Hirawat made statements about the importance of the approval process Liso-cel, the close monitoring of it, and the necessary site inspection: "what I can say today is the FDA has informed us that they will require inspection of both our facilities in Washington State as well as the manufacturing organization for the vector, which is located in Texas….We are working very closely with the FDA to keep this application on track. And as you know, the PDUFA date is in November… the importance of this application is very, very high for us. And I think it is also as important from the FDA and we will continue to work closely with them so that we can bring this product to the patients as soon as possible."

g. In a Zoom panel discussion hosted by Endpoints News on September 15, 2020, Hirawat was asked about Liso-cel and responded: "we have a continuous dialogue with the FDA, and FDA has provided us the good guidance, and we continue to

work. Our PDUFA date, everybody knows, is in November, so we'll just keep on that."

h. On September 21, 2020, Defendant Hirawat participated in an investor event at the European Society of Medical Oncology, at which he stated that with respect to Liso-cel, "we continue to work with the FDA in terms of assessing when the inspections will be. These plants have not yet been inspected. Just a reminder, we do have a breakthrough therapy designation. I remind you that we have a PDUFA date in November. As soon as the FDA will inform us, we'll certainly take that into account. But right now, we don't have a date for inspection at the time, and so they have not been inspected yet."

i. On September 24, 2020, Scrip Pharma Intelligence published an article concerning a then-recent interview with Defendant Hirawat, during which Hirawat noted that "at this time, the liso-cel and ide-cel programs are on track to meet their approval goals."

j. On the November 5, 2020 earnings call about the Company's third-quarter earnings, Bristol executives were asked for an update on the FDA's Liso-cel and Ide-cel review, to which Hirawat responded: "From liso-cel perspective, not much to share, except for the fact that we've already communicated. We continue our dialogue with the regulatory agencies. We've had the inspection done for the facility in Washington. And as we have communicated earlier that we don't have any scheduled inspections for the second facility, which is one—which is independent of the other facility. For liso-cel, we have a PDUFA date on 16th of

November. For ide-cel, same thing, we are continuing our dialogue and that we have a PDUFA date of March 27 of 2021.

k. In response to a second question in that same call, Defendant Hirawat stated: "For liso-cel, as we mentioned earlier, as we disclosed in the past, FDA has informed the Company that both our plants in Washington as well as the one in Texas need to be inspected. They've been able to inspect our plants in Bothell, Washington at this time but have not scheduled any inspection of the second plant…. Conversations with the agencies are going well, and we look forward to seeing the—hopefully, the approval at some point to be able to bring it to the patients as soon as possible. We'll obviously let you know as soon as we get the decision. We are not going to comment obviously specifically about the dialogue around inspections, et cetera. We're generally very happy with the dialogue that has been happening."

2. In a November 16, 2020, Press Release, Bristol Stated that it Was "continu[ing] to work closely with the FDA to support the ongoing review of the BLA for liso-cel."

171. Market analysts and investors believed Defendants' representations. For example, based on Defendants' representations, at the close of the Merger, analysts at Guggenheim Partners and elsewhere projected that all three drugs would be approved well ahead of their Milestone dates. One analyst noted the FDA's original PDUFA date of August 17, 2020 was a "positive step" for CVR holders. Indeed, even after COVID-19 began, analysts remained optimistic that the CVR was still likely to be fulfilled.

172. While Bristol's executives arguably had an obligation to stay abreast of the

approval process even before the above comments were made[11]—especially since it promised to exercise "diligen[ce]" in its Proxy statement—they undeniably were under such an obligation afterwards. As such, Bristol's executives—speaking on behalf of the corporation as a whole—were either recklessly misleading about the degree to which they were informed of Liso-cel's FDA approval, or they indeed had actual knowledge of the approval process.

3. Bristol Executives were Informed About the Company's Unpreparedness and Failures to Get Liso-Cel Approved in Time

173. Defendant Caforio personally negotiated the Merger Agreement with Celgene and personally insisted on the inclusion of the unusual three milestone "all or nothing" clause in the Merger Agreement that was the predicate act for the schme as it allowed Bristol to avoid paying Celgene shareholders $6.4 billion if FDA approval of Liso-cel, Ozanimod, or Ide-cel was delayed past its Milestone date. Individual Defendants Sato, Arduini, Bertolini, Emmens, Grobstein, Lacy, Paliwal, Samuels, Storch, Vousden, as members of Bristol's Board of Directors, discussed and approved the unusual three milestone "all or nothing clause" in the Celgene Merger Agreement. Defendant Caforio signed the Merger Agreement.

174. Defendant Caforio and the Bristol Board carefully monitored the progress of the FDA trials for the three drugs Milestone Drugs vis a vis their Milestones as evidenced by the fact that the Defendants Caforio and Bancroft told Guggenheim Partners, a major investor, on or around November 7, 2019, that "oversight of the CVR is a ***board-level responsibility***…" (emphasis added).

[11] As CW #10 observed during Plaintiffs' investigation, individuals like Defendant CEO Caforio would have had a "fiduciary duty to his shareholders to know about" the FDA approval process for liso-cel, and "if [Bristol] claim[s] they didn't then they aren't meeting their obligations." According to CW #10, Caforio "should have been apprised of the situation" and should have known about all FDA communications.

175. Like with all major pharmaceutical companies, it was regular practice for Bristol/FDA correspondence to be dispatched directly to Defendant Caforio. Indeed, FDA Establishment Inspection Report ("EIR") and inspection warning letters were regularly addressed to Caforio personally..[12] To imagine that Caforio, who is regularly kept ***personally*** abreast of FDA communications for even Bristol's marginal drugs and facilities, would not have known about the developments regarding Liso-cel's approval, is unimaginable.

176. Critically, the Executive 10(b) Defendants not only should have known, but indeed ***did know*** about the Company's repeated intentional "missteps" that delayed the Liso-cel approval until just after the CVR deadline.

177. CW #9, a former Bristol employee who was part of a team that contributed updates to senior management in 2020, stated that Defendant CEO Caforio would have been aware of underlying issues regarding the FDA approval process for Liso-cel, including the major amendment delay and the Form 483s from the FDA. According to CW #9, Caforio and his co-Executive Defendants were included as part of the communication updates. Indeed, CW #9 noted that during the pending approval of Liso-cel, priority attention from management was given to the program, including commercial readiness and the status of the manufacturing sites. As such, according to CW #9, Liso-cel program updates were shared with a high degree of frequency to senior leadership, including at times to CEO Caforio. According to CW #9, the Executive Defendants' updates would have come in the form of regular communication on the pending approval status and ad hoc communication or meetings for any escalating issues, including major FDA communication.

[12] *See, e.g.,* https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/abraxis-bioscience-llc-633713-10312022

4. Bristol's Corporate Structure Was Arranged *For The Purpose* Of Keeping Executives Informed About Matters Like Liso-cel's Approval

178. Bristol's Science & Technology Committee is responsible for overseeing Bristol's research and development ("R&D") and ***pipeline of new pharmaceuticals***. According to the Science & Technology Committee's 2019 Charter as well as Bristol's public SEC filings, the Science & Technology Committee is responsible for, among other things: (1) ***overseeing and regularly reviewing Bristol's pipeline***; (2) assisting in setting pipeline performance metrics under the Company's incentive compensation programs and reviewing performance results; and (3) advising Bristol's Board on the Company's progress in achieving near-term and long-term R&D goals; and (4) coordinating with the Integration Committee—of which Defendant CEO Caforio was a member—in overseeing the company's integration of Bristol and Celgene's pipelines into a combined portfolio. Following the Merger, the Science & Technology Committee also worked with the Integration Committee on "[o]verseeing the company's progress towards integrating the company's and ***Celgene's pipelines*** and alliances into a combined portfolio, and monitoring ***portfolio prioritization and execution."*** (emphasis added).[13]

179. By virtue of their service on Bristol's Science & Technology Committee and Integration Committee, several Individual 10(b) Defendants were made aware of the issues with Liso-cel's FDA approval process and were aware that Liso-cel would not be approved by the Milestone Deadline. From 2019 through 2020, Defendants Sato, Arduini, Emmens, and Vousden each served on the Science & Technology Committee, and the Committee held twenty (20) meetings during that timeframe.

[13] Bristol Myers Squibb, Schedule 14A SEC Filing (March 25, 2020), https://www.sec.gov/Archives/edgar/data/14272/000114036120006834/nc10007007x1_def14a.htm.

180. Additionally, Bristol's Integration Committee was responsible for ***overseeing all aspects of the Celgene integration*** and providing advice and assistance to Bristol's management with respect to the integration. According to proxy statements filed by Bristol with the SEC, the Integration Committee's responsibilities included: (1) overseeing the company's progress in achieving launch readiness and commercial execution for the ***near-term product launch opportunities***; (2) working with the Science & Technology Committee to oversee the Company's progress towards ***integrating Celgene's pipeline and monitoring portfolio prioritization and execution***; and (3) providing ***regular reports to the Board on the progress of the Merger integration***, including at each regularly scheduled Board meeting. From 2019 through 2020, Defendants Caforio, Arduini, Emmens, Paliwal, and Vousden each served on the Integration Committee, and the committee held nine (9) meetings.

181. The communication between the FDA and Bristol was extensive during the approval process of Liso-cel. The FDA notified Bristol of the status of its review of the BLA, the original and amended PDUFA dates, and the results of the Lonza and Juno facility inspections and responses. Throughout all of this, it was the job of both the Science and Technology Committee and the Integration Committee to keep Bristol's executives abreast of any developments regarding the approval process for Liso-cel and the rest of the Milestone Drugs.

182. In addition, Bristol committed considerable person-power to engaging with the FDA. Letters exchanged between the FDA and Bristol cc'ed as many as forty individuals at Bristol, including individuals from Global Regulatory Sciences, Global Risk Management, Global Drug Development, and Global Development Operations. Similarly, dozens of Bristol employees attended the March and September 2020 meetings with CBER, including representatives from Bristol's divisions of Global Drug Development; Global Regulatory Sciences; Global Risk

Management; Global Drug Safety; Global Medical Affairs; and Global Development Operations.

G. Bristol Misses the Liso-cel Milestone Approval Date by Thirty-Six Days

183. Following the three-month delay caused by Bristol's filing a Major Amendment to the Liso-cel BLA, the two facility inspections' resulting in FDA Form 483s identifying violations, and the inadequate responses to those Form 483s, the Liso-cel Milestone date passed on December 31, 2020, without FDA approval.

184. The very next day, January 1, 2021, Bristol stated that "[b]ecause the milestone of approval of [L]iso-cel by December 31, 2020 was not met, the CVR Agreement has automatically terminated in accordance with its terms, the security will no longer trade on the NYSE, and the CVRs are no longer eligible for payment."

185. As Defendants knew, FDA approval would soon follow. On February 4, 2021, Executive Vice President Boerner said on an earnings call, "[w]e're obviously very excited about the opportunity to launch Liso-cel in [diffuse large B cell lymphoma]. We expect that imminently. We are obviously going to be very much focused on ensuring at launch that sites are activated very quickly, that we're able to get patients efficiently moved on to therapy." The following day—just thirty-six days after the Liso-cel milestone—the FDA approved the Liso-cel BLA.

186. For Bristol's and Individual Defendants' finances, the near miss of the Liso-cel Milestone was perfect: it allowed Bristol to avoid the $6.4 billion payout but to start profiting from Liso-cel almost immediately after.

187. In the 36 days between the Liso-cel Milestone and the approval, more than 1,500 Americans died of non-Hodgkin's lymphoma. In the 5.5 months between the original PDUFA date and approval, more than 9,000 Americans died of the disease.

H. Bristol Delays the Ide-cel Approval Process to Further Ensure a CVR Deadline is Missed

188. At the same time Bristol was submitting deficient filings that caused a delay in the FDA approval process for Liso-cel, it was maximizing its odds of avoiding the $6.4 billion CVR payout by also submitting deficient filings for Ide-cel, the cell therapy with the third and final CVR milestone date. Like Liso-cel, Ide-cel had also received designation as a Breakthrough Therapy. On March 31, 2020—*after* having already been asked by the FDA to provide additional information for the Chemistry, Manufacturing, and Controls section of the Liso-cel BLA—Bristol announced that it had submitted a BLA for Ide-cel. This BLA ***also*** had a materially deficient Chemistry, Manufacturing, and Controls section, which prompted the FDA to issue a Refuse to File letter on May 13, 2020, thus delaying the approval process for Ide-cel as well.

189. Under the FDA's Standard Operating Policy and Procedure 8404, a Refuse to File decision is reserved for submissions containing "omissions of clearly necessary information (*e.g.*, information required under the statute or regulations) or omissions or inadequacies so severe as to render the application incomplete on its face and where the omissions or inadequacies are obvious." According to a study by the Journal of the American Medical Association, only 4% of submissions for approvals of new drugs trigger Refuse to File letters, and the overwhelming majority of the Refuse to File decisions issued by the FDA were the result of substantive issues with the drug at issue, as opposed to an incomplete submission like done by Bristol for Ide-cel.

190. As an analyst for Mizuho noted, such a deficient submission was extremely unusual as Bristol "knows how to complete a regulatory application. It seems to complete regulatory applications, in general, just fine in the US and for [Ide-cel] it seems to have had no issue in Europe." Observing that the Milestone date for Ide-cel was March 31, 2021, an analyst from Morgan Stanley noted that Bristol's plan to resubmit the BLA in July "would take it down to the wire and leave no room for any further delays (including labeling discussions), since Priority

Review timeline for a BLA is eight months from date of filing."

191. Bristol thus put itself in striking distance—just one more insufficient submission or poorly prepared facility or slow labeling discussion—of missing the Ide-cel Milestone. But after missing the Liso-cel December 31, 2020 Milestone, further delay of the Ide-cel approval process was no longer in Bristol's economic interest because the CVR payment was terminated regardless. On March 26, 2021—five days before the Milestone date for Ide-cel—the FDA approved Ide-cel.

I. Liso-Cel's Untimely Approval was Not Due to the COVID-19 Pandemic

192. Outside analysts, internal Bristol employees, and the FDA Biologics Expert all agree that COVID-19 cannot explain Bristol's failure to get Liso-cel approved by the Milestone date.

193. Mizuho analyst Salim Syed, who followed the Bristol BLA approval process, reviewed the primary source FDA documents and performed an empirical study on Bristol's Liso-cel timeline versus that of its competitors. Syed noted that Bristol "***may not have been entirely thorough***" during the application and review process and that "***[a]pplications are either complete or not—this is a very binary concept.***" Syed similarly challenged Bristol's contention that the failure to obtain approval for Liso-cel was solely due to COVID-related inspection delays, stating that could not be "the whole story" because the inadequate BLA information was submitted months prior to the pandemic.

194. According to CW #10, who was an executive in the quality department of Celgene/Bristol, Bristol cannot blame the delay of approval of Liso-cel on COVID-19 alone, because even after the FDA inspected the Lonza facility, it still did not pass inspection.

195. The FDA Biologics Expert agrees. First, according to the FDA Biologics Expert, Bristol had failed to adequately prepare the Juno facility for inspection for reasons wholly unrelated to the global pandemic. For one, Bristol failed to adequately address its mold trends at

the Juno facility: mold is a serious facility issue while Bristol failed to address, indicating that Bristol's Corrective and Preventative Actions were ineffective. Mold issues have nothing to do with COVID-19. For another, any company that is using viral vectors like those at Bristol's facilities must have proven disinfectants in use, but the Juno facility was unprepared to show it had such disinfectants in use. Again, a failure to demonstrate adequate disinfectant use is not COVID related.

196. Second, according to the FDA Biologics Expert, Bristol's Response to the November 5, 2020, Form 483 was obviously inadequate. For example, regarding Observation 1, the response was inadequate because Bristol changed only two Standard Operating Procedures (SOPs), and Bristol focused on the Corrective Action rather than the Preventative Action, even though a large pharmaceutical company like Bristol "would know" that the FDA would instead be looking for a systemic approach. Regarding Observation 2, according to the FDA Biologics Expert, Bristol's response was wholly inadequate because it (1) was incomplete; (2) contained internal contradictions regarding whether deviations were misclassified or not; and (3) Bristol offered a remediation of six weeks, when two weeks would have sufficed. According to the FDA Biologics Expert, both of these responses are so deficient for a company like Bristol, which regularly engages in the FDA approval process, as to justify an inference of reckless or deliberate delay by Bristol. And the failure to respond to the Form 483 had nothing to do with the COVID pandemic.

1. Liso-cel Was Approved 415 Days After Celgene's BLA Submission, More Than Twice the 194-Day Average For Similarly Situated CAR-T Therapies, Including Those Approved During COVID-19

197. Bristol obtained FDA approval for Liso-cel ***415 days*** after its initial BLA filing—***more than twice*** the 194-day average time for FDA approval of similar and ***less effective*** therapies:

CAR-T Therapy	Manufacturer	BLA Submission Date	FDA Approval Date	Days from BLA Submission Date to FDA Approval
Liso-cel	***Bristol***	***12/19/2019***	***2/5/2021***	***415***
Tecartus	Gilead (Kite)	12/11/2019	7/24/2020	226
Kymriah	Novartis	3/28/2017	8/30/2017	155
Yescarta	Gilead (Kite)	3/31/2017	10/19/2017	202

198. As set forth above, Bristol's direct competitor, Gilead, submitted a BLA for its rival CAR-T therapy, Tecartus, on December 11, 2019, just eight days prior to the submission of the BLA for Liso-cel. Tecartus's PDUFA date was August 10, 2020—just seven days before Liso-cel's original PDUFA date of August 17, 2020. The FDA approved Tecartus on July 24, 2020—over half a year ***before*** the approval of Liso-cel. If Liso-cel had taken the same amount of time for FDA approval as Gilead's similar CAR-T therapy Tecartus, it would have made the CVR Milestone date ***with 153 days to spare***.

199. Notably, Gilead obtained FDA approval for Tecartus during the height of the COVID-19 pandemic. At the same time, Bristol falsely represented to investors that FDA approval for Liso-cel were delayed due to pandemic-induced issues impacting FDA Pre-License inspections of Liso-cel's manufacturing facilities. In other words Gilead—a similar company to Bristol—during the ***same*** time period, during the ***same*** Covid-19 pandemic and dealing with the ***same*** regulatory agency managed to obtain approval for a very similar drug in about ***half*** the time it took Bristol to obtain approval for Liso-cel.

200. This illustrates that Bristol's failure to get Liso-cel approved in the same time as Gilead got Tecartus approved was not due to COVID delays, as Bristol claimed, as such delays equally impacted Tecartus during the same period. Instead, it was due to Bristol's failure to submit a complete BLA application, its delay in providing the missing information upon request, and its

refusal to adequately prepare its manufacturing facilities by correcting known problems.

2. The 415-Day Approval Time Was Nearly Twice that of Every Other Original BLA/NDA Submitted by Both Celgene and Bristol From 2014-2020

201. Bristol and Celgene submitted nine therapies for FDA approval between July 2014 and 2020. As set forth in the chart below, the average time for FDA approval of these therapies was 221.6 days:

Original NDA and Original BLA Approvals Filed By Bristol and Celgene, 2014-2020				
Applicant	**Proprietary Name**	**FDA Received Date**	**Approval Date**	**Days from FDA Received Date to Approval Date**
Bristol	Opdivo	7/30/2014	12/22/2014	145
Bristol	Opdivo	7/30/2014	12/22/2014	145
Bristol	Evotaz	4/4/2014	1/29/2015	300
Bristol	Daklinza	3/31/2014	3/4/2015	338
Bristol	Empliciti	6/29/2015	11/30/2015	154
Celgene	Idhifa	12/30/2016	8/1/2017	214
Celgene	Reblozyl	4/4/2019	11/8/2019	218
Celgene	Zeposia	3/25/2019	3/25/2020	366
Celgene	Onureg	3/3/2020	9/1/2020	182

Shortest Days to Approval	145
Average Days to Approval	*221.6*

202. By contrast, it took Bristol 415 days to get Liso-cel approved—nearly ***double*** that of the average, and forty-nine days longer than ***any*** of the other nine drugs approved during the same time frame, despite the fact that Liso-cel had the added benefit of being a designated

Breakthrough Therapy and a Regenerative Medicine Advance Therapy with Priority Review status.

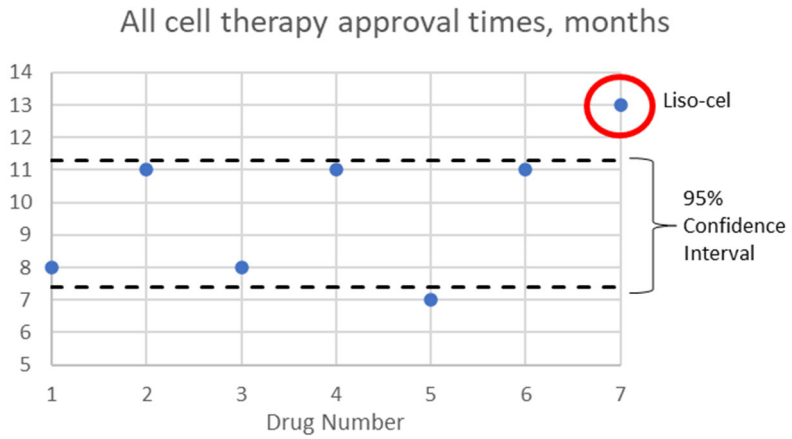
3. There Is a Statistically Significant Difference Between Approval Time for Liso-Cel and Approval Times for Other Cell or Gene Therapies During the Covid-19 Pandemic

203. According to the FDA Biologics Expert, to conduct an apples-to-apples comparison, one should consider ***all parenteral cell/gene therapy biologics (Advanced Therapies)*** approved by FDA/CBER/Office of Tissues and Advanced Therapies ("OTAT") at the time Liso-cel was approved, and during the pandemic, except for tissue type products (non-parenteral), and cord blood (minimally manipulated) as these are not Advanced Therapies, and except for those manufactured outside of the U.S. where FDA/Team Biologics was not inspecting at the time. After excluding those biologics, one is left with biologics that are directly comparable to Liso-cel, because they all undergo identical approval processes within CBER and OTAT and were inspected by Team Biologics in-person and CBER virtually at the time, like Liso-cel, a parenteral product. In fact, such an approach is ***conservative*** because it would include comparators that were ***not subject to priority review***, which would therefore be ***expected to be approved more slowly than Liso-cel***.

204. According to an analysis conducted by the FDA Biologics Expert, there is a statistically significant difference between the 13-month approval time for Liso-cel and the approval times for the comparators described in paragraph 203.

205. According to the FDA Biologics Expert, these six comparator drugs took between seven and eleven months to be approved by the FDA. Based on these historical examples, the expected time to approval for a drug like Liso-cel would be 7.4 to 11.3 months, ***a range considerably lower than the thirteen months it took Bristol to approve Liso-cel.*** Indeed, the thirteen-month approval time for Liso-cel falls outside the 95% confidence interval for FDA

approval time for similar drugs. In other words, Bristol's thirteen-month approval timeline for Liso-cel is a ***statistical anomaly***, ***even as compared to similar drugs undergoing the approval process during the COVID-19 pandemic.***



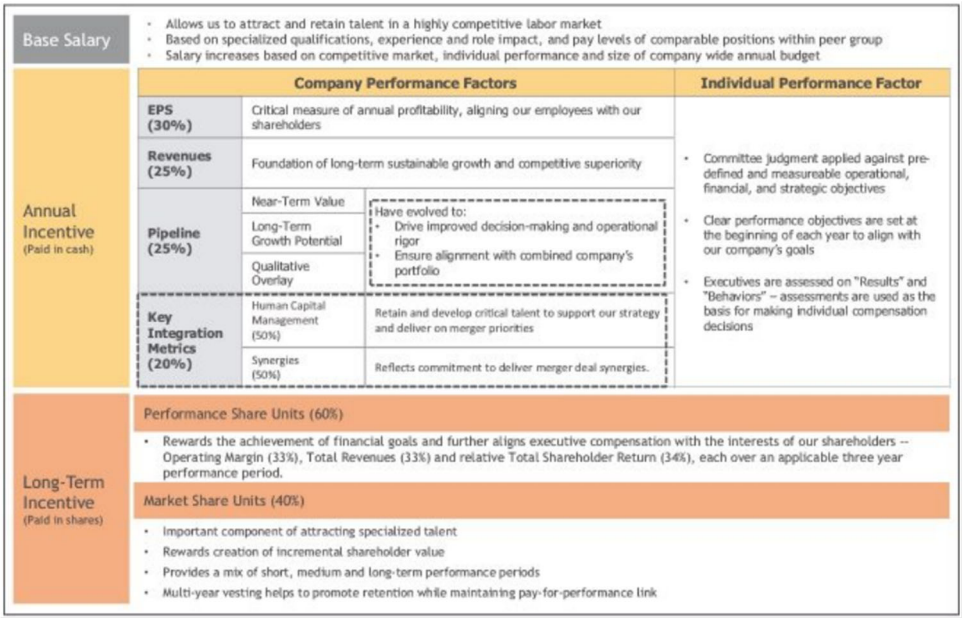
J. Defendants Benefitted Financially from the Company's Miss of the Liso-cel Milestone

206. Defendant CEO Caforio and the rest of the Bristol executive team were desperate to improve the Company's profitability at the time of the Merger. From the time that Caforio took over as Bristol's CEO in May 2015 until the time that the Merger occurred in January 2019, Bristol's stock price had cratered nearly 30%. Indeed, Bristol had been subject to multiple critical press reports regarding its string of failures.[14] As such, there was immense pressure on Caforio and the other Individual Defendants to bring the therapies brought over in the Merger to market in as profitable a manner as possible. By avoiding the $6.4 billion payout in 2021, Caforio and the other Individual Defendants increased Bristol's net earnings in 2021 from $600 million to $7.0 billion – ***a staggering 1100% increase***.

[14] *See, e.g.*, Evelyn Cheng and Meg Tirrell, *Bristol clobbered—shares drop 17%—after failed drug test*, CNBC (Aug. 5, 2016); Carly Helfand, *Another Opdivo setback for Bristol, this time on the combo front, widens Merck's immuno-oncology lead*, Fierce Pharma (Jan. 20, 2017); Matthew Herper, *More Questions Than Answers For Bristol-Myers*, Forbes (Feb. 5, 2018).

207. In March 2020, Bristol released a proxy statement in which it laid out its plan for executive compensation. Bristol executives' compensation packages consisted of three main parts: a base salary, an annual incentive award, and a long-term incentive award.

208. The annual incentive award was based in significant part on company performance, which was determined based on several factors: earnings per share (for which performance relative to the company's annual target was worth 30% of the annual incentive calculation), revenues (25%), pipeline (25%), and key integration metrics (20%). The pipeline metric was split between near-term value (*i.e.*, submissions and approvals) and long-term growth potential. The Company's 2020 proxy statement provided the following visual under the header "2020 Compensation Plan: Design Supports Successful Integration":



209. The proxy statement explained that the near-term value factor in the pipeline metric took into account the CVR milestones and thus created an incentive for Bristol's leadership to hit the CVR milestones:

> Solidifying the direct line of sight into tangible pipeline objectives aligns our executives' interests with our shareholders outcomes, ***including those shareholders holding CVRs***. In particular, ***the 2020 pipeline goal will take***

> ***into account the specific milestones associated with the CVR***, namely, FDA approval in specified indications of *ozanimod* (by December 31, 2020), *liso-cel* (JCAR017) (by December 31, 2020), and *ide-cel* (bb2121) (by March 31, 2021).

210. Accordingly, investors believed that the Individual Defendants had a financial incentive to ensure approval of the CVR therapies before the Milestone dates. For example, the investment bank Mizuho Securities USA published a report titled "ICYMI: BMY Executive Compensation Directly Tied to CVR Working," in which it quoted the above language and graphic from the proxy statement and gave the CVR a "Buy" rating. Throughout the Class Period, Mizuho continued to remind investors that management had an incentive to reach the CVR, noting, for instance, "BMY does not have incentive here to torpedo the data. Recall, ***mgmt comp is partly tied to this CVR working***."

211. In reality, though, the CVR milestones played no meaningful role in determining Bristol executives' salaries. A 2021 proxy statement describing the executives' 2020 compensation explained that Bristol's Compensation Committee determined that the company had exceeded its targets for each aspect of company performance, ***including the pipeline metric***:

Performance Measure	Target	Actual	% of Target	Resulting Payout Percentage
Non-GAAP Diluted EPS(1)	$6.09	$6.44	105.7%	115.79%
Total Revenues, Net of Foreign Exchange ($=MM)	$41,742	$42,523	101.9%	115.45%
Pipeline Score	3.0	4.0	133.3%	126.09%
Key Integration Metric – Synergy	$833	$1,427	171.3%	152.17%
Key Integration Metric – Human Capital	3.0	4.0	133.3%	126.09%
Total	—	—	**121.0%**	**122.95%**

212. This determination supported annual incentive awards worth millions of dollars for Bristol's executives, including the following list of named executives (the first two of whom are Individual Defendants):

Executive	Target Incentive Award	Applying Company Performance Factor(1)	Actual Payout(2)
Giovanni Caforio, M.D.	$2,531,352	$3,112,298	$4,201,602
David V. Elkins	$1,015,102	$1,248,068	$1,684,892
Rupert Vessey M.A, B.M., B.Ch., F.R.C.P., D.Phil.	$1,022,541	$1,257,214	$1,697,239
Sandra Leung	$1,068,555	$1,313,789	$1,642,236
Christopher Boerner, Ph.D.	$952,940	$1,171,639	$1,581,713

213. The Compensation Committee determined that the Company had performed especially ***well*** on the near-term-value factor of the pipeline score – the metric that was purportedly supposed to provide a financial incentive to meet the CVR milestones – by making 52 regulatory submissions and approvals in 2020. The 2021 proxy statement describing the scoring of the annual incentive award gave no indication that the failure to hit the Liso-cel milestone affected the pipeline score (or that it negatively affected the executives' compensation in any other way). To the contrary, the proxy statement described the mere *submission* of the Liso-cel regulatory filings as a success for the company, stating that "among other achievements, in 2020, we . . . submitted regulatory filings for CAR-T therapies, liso-cel and ide-cel in the U.S." In other words, despite having told investors that Bristol's executive compensation package created a meaningful incentive for the Company to hit the CVR milestones, the Compensation Committee gave the executive Defendants high marks on the part of the compensation package that was purportedly supposed to take the CVR milestone into account – and even treated the Company's progress in the Liso-cel approval process as a success in 2020 despite having *missed the CVR milestone*.

214. Not only were Defendants financially unscathed by the miss of the Liso-cel milestone—they significantly benefited from it. The Company avoided a $6.4 billion payout in 2021. That payout would have been nearly as big as the Company's entire $7.0 billion in net earnings in 2021, which followed a year in which the Company incurred a net *loss* of $9.0 billion. According to analysts at Guggenheim Partners, holding onto the $6.4 billion in cash was worth *$3 per share*—or 5% of the valuation of the Company.

215. Avoiding this payout also directly affected Individual Defendants' finances through its impact on the value and dividends of Bristol common stock. The director Defendants were required to own at least half a million dollars' worth of Bristol common stock, and the executive Defendants also owned millions of dollars' worth of Bristol common stock. Furthermore, the executive Defendants' long-term incentive plan depended on relative total shareholder return, a measure that accounts for stock performance and dividend payments—two factors that would have been negatively impacted by the Company making a $6.4 billion payment that would have reduced the Company's valuation by 5% in one fell swoop.

216. At the end of 2020, the Company held a net debt position of $34.4 billion. On February 4, 2021, with $6.4 billion of cash that would not need to be paid to CVR holders, Bristol announced that it would be paying off $4 billion of its debts early.

K. Defendants Make a Concerted Effort to Conceal Their Fraud

217. During the Class Period, Defendants repeatedly cited COVID-19 as a risk to the process of meeting the CVR Milestones and a cause of delays in the approval process. And after missing the Milestone a spokesperson for Bristol stated, "We believe in the strength of our BLA filing for Liso-cel and that the FDA would have been able to complete the review at the revised, extended PDUFA date (11/16/2020) within the CVR timeline had it not been for COVID-related inspection delays." But, in reality, Defendants were using COVID-19 as cover for the real cause of delay – their own deliberate or reckless actions. In 2020, the FDA approved 53 drugs, the second highest number in two decades, including 20 cancer drugs, in addition to 13 BLA approvals (including Tecartus, Gilead's CAR-T therapy that was set on a nearly identical approval timeline as Liso-cel but which was approved in 189 fewer days). In other words, at the same time Bristol claimed COVID-19 inspection delays at the FDA were hampering the Liso-cel approval, the FDA was approving record amounts of other drugs. It is not credible that COVID-19 inspection delays

at the FDA only affected Liso-cel and not the more than *fifty* other drugs the FDA approved that same year.

218. In addition, following Bristol's miss of the Liso-cel Milestone, Bristol took a number of steps to keep investors from learning what caused the delay in the approval. For example, on December 29, 2020, the trustee for the CVR holders sent a letter to Bristol requesting certain books and records to allow it to assess whether Bristol had made diligent efforts to reach the CVR milestones. Despite the trustee having the right to make such a books-and-records request under the CVR Agreement, Bristol refused. To date, it still has not complied with the trustee's request.

V. THE MATERIALLY FALSE AND MISLEADING STATEMENTS

219. As set forth below, Defendants made numerous materially false statements and omissions of material fact concerning the CVRs and the development and approval of Liso-cel.

A. False and Misleading Statements in the Registration Statement and Joint Proxy

220. On February 20, 2019, Bristol, together with Celgene, filed a Registration Statement, which included the portions of the Joint Proxy at issue here. On February 22, 2019, Bristol, together with Celgene, filed the Joint Proxy, soliciting votes on the proposed Merger:

> Dear Bristol-Myers Squibb Company Stockholders and Celgene Corporation Stockholders: **On behalf of the boards of directors of Bristol-Myers Squibb Company** ("Bristol-Myers Squibb") and Celgene Corporation ("Celgene"), we are pleased to enclose the joint proxy statement/prospectus relating to the merger of Celgene with a wholly-owned subsidiary of Bristol-Myers Squibb, which is referred to in this notice as the merger, pursuant to the terms of a merger agreement entered into by Bristol-Myers Squibb and Celgene on January 2, 2019,

221. The statements set forth below were repeated verbatim in both the Registration Statement filed February 20, 2019, and the Joint Proxy filed February 22, 2019.

222. The Joint Proxy and Registration Statement falsely and misleadingly stated there

was a strong possibility that the Milestones would be met, and that Bristol would in good faith use diligent efforts to meet them. Specifically, the Joint Proxy and Registration Statement informed Celgene shareholders that "***Celgene's key late-stage product candidates, which are expected to launch in 2019 and 2020, are ozanimod, fedratinib, luspatercept, [Liso-cel], and [Ide-cel]***." Joint Proxy at 82. The Joint Proxy and Registration Statement falsely and misleadingly stated that "***Bristol-Myers Squibb management provided an estimate of the probability of achieving the three FDA approvals required to trigger the $9 payment under the CVR agreement to the BMS Board in connection with its evaluation of the merger, and to each of Morgan Stanley, Dyal Co. and Evercore for purposes of their respective financial analyses and opinions. This estimate [] was 45%***." Joint Proxy at 157.

223. The above statements were materially false and misleading and/or omitted material facts because, among other things, they omitted that Bristol was not going to use diligent efforts to meet all three deadlines, and intended to slow-roll the FDA application process for Liso-cel and Ide-cel so that it would miss at least one FDA milestone and avoid making the $9 CVR payment worth $6.4 billion.

224. The Joint Proxy and Registration Statement also made a series of false and misleading statements regarding the value of the CVRs. The Joint Proxy and Registration Statement stated that "***The CVRs are contingent value rights to be issued by Bristol-Myers Squibb as part of the merger consideration to Celgene stockholders and certain holders of Celgene equity awards. Each CVR represents the right to receive a one-time cash payment of $9.00 if the [] FDA, approves, by the [Milestones]***." Joint Proxy at 4, 217.

225. Critically, the Joint Proxy and Registration Statement misrepresented to Celgene shareholders that Bristol would engage in "diligent efforts" to achieve the CVR Milestones.

Specifically, the Joint Proxy and Registration Statement informed shareholders that:

> Bristol Myers Squibb has agreed to use "diligent efforts" to achieve the CVR milestone. "Diligent efforts" means, with respect to [Ide-cel], [Liso-cel] or Ozanimod, efforts of a person or entity to carry out its obligations in a diligent manner using such effort and employing such resources ***normally used by such person or entity in the exercise of its reasonable business discretion relating to the research, development or commercialization of a product***, that is of similar market potential at a similar stage in its development or product life, taking into account issues of market exclusivity (including patent coverage, regulatory and other exclusivity), safety and efficacy, product profile (including tolerability and convenience), the competitiveness of alternate products in the marketplace or under development, the launch or sales of one or more generic or biosimilar products, actual or likely pricing/reimbursement [Ide-cel], [Liso-cel] or Ozanimod, the likely timing of such product's entry into the market, the likelihood of regulatory approval of such product and applicable labeling, and the profitability of such product, and other relevant factors, including technical, commercial, legal, scientific, and/or medical factors, based on conditions then prevailing.

Joint Proxy at 219. The Joint Proxy and Registration Statement also attached the Form CVR Agreement which disclosed the same to Celgene shareholders. *Id*. at B-2, B-22.

226. The above statements were materially false and misleading and/or rendered misleading by the omission of material facts because, among other things they misstated the status of the applications for FDA approval and omitted that Bristol was not going to use diligent efforts to meet all three deadlines, and intended to slow-roll the FDA application process for Liso-cel and Ide-cel so that they would miss at least one FDA milestone and avoid making the $9 CVR payment.

227. The Joint Proxy and Registration Statement also made a series of risk disclosures regarding the potential diminished value of the CVRs. Specifically, the Joint Proxy and Registration Statement stated, "***Your right to receive any future payment on the CVRs will be contingent upon the achievement of certain agreed upon U.S. regulatory milestones within the time periods specified in the CVR agreement . . . . Accordingly, the value, if any, of the CVRs is speculative, and the CVRs may ultimately have no value***." Joint Proxy at 50.

228. The Joint Proxy and Registration Statement similarly stated that:

> There is also uncertainty regarding the fair market value of the CVRs and whether any payment will ultimately be realized on the CVRs. Accordingly, at the time of the Celgene special meeting, Celgene stockholders will not know or be able to determine the market value of the merger consideration they would be entitled to receive upon completion of the merger.

Joint Proxy at 39.

229. The above statements were materially false and misleading and/or rendered misleading by the omission of material facts because, among other things they misstated the status of the applications for FDA approval and omitted that Bristol intended to slow-roll the FDA application process for Liso-cel and Ide-cel so that they would miss at least one FDA milestone and avoid making the $9 CVR payment.

230. Following the issuance of the Registration Statement and Joint Proxy, on November 7, 2019, analysts of Guggenheim Partners, an investment and financial advisory firm, published a report recounting what they were told in a meeting with Defendants Caforio and Bancroft (and CCO Chris Boerner) that had occurred on November 7 or shortly before:

> Achievement of key milestones associated with the CELG pipeline CVR is on track; despite substantially high conviction in the components of the CVR, there are no plans to buy it back early. Mr. Bancroft noted that the tradable Contingent Value Right (CVR) is structured to pay CELG shareholders $9.00 in cash one-time if FDA approval is secured for all three products in ozanimod (by YE20), liso-cel/JCAR017 (by YE20) and bb2121 (by the end of 1Q21). **Management emphasized several points, including (1) oversight of the CVR is a board-level responsibility and BMY is highly motivated to pay out the CVR because of the importance of the CELG pipeline to the company's future value**; but (2) BMY has no plans to buy back the CVR early, either via open market purchases or a tender primarily because of the availability of asymmetric information available to BMY vs. the shareholders of the CELG CVR. As it relates to the CVR, we expect shares to trade purely on the events and probability that all three events are achieved in the allotted timeline.

231. These statements were materially false and misleading because they omitted that (i) Bristol intended to slow-roll the FDA application process for Liso-cel and Ide-cel in various

ways so that it would miss at least one FDA milestone and avoid making the $6.4 billion CVR payment; (ii) Bristol's financial incentives were such that it would profit most if it received FDA approval of one of the CVR drugs soon *after* its Milestone date; and (iii) Bristol did not intend to buy back the CVRs because it did not intend to meet all the Milestone Dates. Yet, at no point throughout the Class Period did Defendants correct this statement, despite having a duty to do so.

B. Defendants' False and Misleading Statements and Omissions Throughout the Class Period

232. In addition to Defendants' false and misleading statements in the Joint Proxy and Registration Statement, Defendants made numerous false and misleading statements and omissions throughout the Class Period.

1. December 8, 2019, Presentation

233. On December 8, 2019, Defendant Hirawat presented at the American Society of Hematology conference. According to a subsequent analyst report, he "reiterated plans to file liso-cel for approval by the end of the year," which the report noted "should ease concerns on timing for the CVR."

234. This presentation was materially false and misleading because it omitted that (i) Bristol intended to slow-roll the FDA application process for Liso-cel and Ide-cel in various ways so that it would miss at least one FDA milestone and avoid making the $6.4 billion CVR payment; (ii) the BLA for Liso-cel was deficient and would require supplemental information in the form of an amendment; and (iii) Bristol knew the supplemental information would be deemed a "major amendment," automatically triggering a three-month extension of the FDA target review date.

2. December 9, 2019, Presentation

235. On December 9, 2019, Defendant Hirawat stated during an investor webcast to discuss highlights from the American Society of Hematology conference, "as we had

communicated right at the beginning of the year for liso-cel submission, we are on track for submitting liso-cel by the end of this year. And we still have a few more days to go in this month. We are on track for that."

236. This presentation was materially false and misleading because it omitted that (i) Bristol intended to slow-roll the FDA application process for Liso-cel and Ide-cel in various ways so that it would miss at least one FDA milestone and avoid making the $6.4 billion CVR payment; (ii) the BLA for Liso-cel was deficient and would require supplemental information in the form of an amendment; and (iii) Bristol knew the supplemental information would be deemed a "major amendment," automatically triggering a three-month extension of the FDA target review date.

3. December 18, 2019, Press Release

237. On December 18, 2019, Bristol announced in a press release that it had submitted the final part of its BLA to the FDA for approval of Liso-cel:

> Bristol-Myers Squibb Company (NYSE: BMY) today announced the submission of its Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for lisocabtagene maraleucel (liso-cel), its autologous anti-CD19 chimeric antigen receptor (CAR) T-cellimmunotherapy comprising individually formulated CD8+ and CD4+ CAR T cells for the treatment of adult patients with relapsed or refractory (R/R) large B-cell lymphoma (LBCL) after at least two prior therapies.
>
> The submission is based on the safety and efficacy results from the TRANSCEND NHL 001 trial, evaluating liso-cel in 269 patients with relapsed/refractory large B-cell lymphoma, including diffuse large B-cell lymphoma (DLBCL).

238. This press release was materially false and misleading because it omitted that (i) Bristol intended to slow-roll the FDA application process for Liso-cel and Ide-cel so that it would miss at least one FDA milestone and avoid making the $6.4 billion CVR payment; (ii) the BLA for Liso-cel was deficient and would require supplemental information in the form of an amendment; and (iii) Bristol knew the supplemental information would be deemed a "major

amendment," automatically triggering a three-month extension of the FDA target review date.

4. February 6, 2020, Earnings Call

239. On February 6, 2020 earnings call, Defendant Caforio stated that "we continue to advance our regulatory filings for liso-cel, ide-cel and CC486."

240. This statement was false and misleading because it omitted that: (i) Bristol was slow-rolling the FDA application process for Liso-cel and Ide-cel in various ways so that they would miss at least one FDA milestone and avoid making the $6.4 billion CVR payment; and (ii) Bristol had already submitted a deliberately insufficient BLA.

5. May 6, 2020, Press Release

241. On May 6, 2020, Bristol issued a press release announcing that its submission of additional information at the FDA's request to supplement its BLA had led to a Major Amendment that would extend the FDA's target approval date to November 16, 2020:

> Bristol Myers Squibb (NYSE: BMY) today announced that the U.S. Food and Drug Administration (FDA) has extended the action date by three months for the biologics license application (BLA) for lisocabtagene maraleucel (liso-cel), a CD19-directed chimeric antigen receptor (CAR) T cell therapy for the treatment of adults with relapsed or refractory (R/R) large B-cell lymphoma after at least two prior therapies. The new Prescription Drug User Fee Act (PDUFA) action date set by the FDA is November 16, 2020.
>
> Subsequent to the submission and acceptance of the BLA and upon FDA request, the company submitted additional information to the FDA, which was deemed to constitute a major amendment to the application and will require additional time for FDA review.

242. This constituted a partial disclosure of the fraud, or materialization of risk previously concealed by the fraud, as the delay was the direct result of deliberate or reckless actions by Bristol to delay the FDA approval process that Defendants had concealed in their prior statements. However, in the same press release, the 10(b) Defendants continued to falsely maintain that Bristol was working diligently to meet the Milestone for Liso-cel:

> **The company will work closely with the FDA to support the continued review of the BLA for liso-cel and is committed to bringing this therapy to patients.**
>
> * * *
>
> **The company is committed to working with FDA to progress both applications and achieve the remaining regulatory milestones required by the CVR.**

243. This statement was false and misleading because it omitted that: (i) Bristol was slow-rolling the FDA application process for Liso-cel and Ide-cel so that it would miss at least one FDA milestone and avoid making the $6.4 billion CVR payment; (ii) the BLA submitted by Bristol for Liso-cel had been deliberately or recklessly deficient so as to require supplemental information constituting a Major Amendment, which would automatically trigger a three-month extension of the FDA's target date; and (iii) Bristol had also submitted a BLA for Ide-cel that was intentionally or recklessly incomplete on its face.

244. Despite Defendants' statements falsely reassuring investors, by the close of the market on May 6, 2020, the value of the CVRs had dropped by 15% since closing the previous day—from $4.43 to $3.75 per share, with volume of more than 11 million shares.

6. May 7, 2020, Form 10-Q

245. On May 7, 2020, Bristol filed a Form 10-Q with the SEC, signed by Defendant Caforio, stating again that the FDA had extended the target approval date, but citing COVID-19 as a possible cause of delay in the approval of Liso-cel:

> **Announced that the FDA has extended the PDUFA date by three months for the BLA for lisocabtagene maraleucel (liso-cel), a CD19-directed CAR T cell therapy for the treatment of adults with relapsed or refractory large B-cell lymphoma after at least two prior therapies. The new PDUFA date set by the FDA is November 16, 2020. . . .**
>
> **It is possible that the COVID-19 pandemic could delay the timing of the FDA's approval decisions for liso-cel and ide-cel, which could have a material adverse effect on our contingent value rights (CVRs).**

> We have submitted BLAs for liso-cel and ide-cel, the two remaining assets underlying our CVRs (the third CVR asset, Zeposia (ozanimod), was approved earlier this year). **These applications are under review by the FDA. Liso-cel has a PDUFA date of November 16, 2020**. We do not yet have a PDUFA date for ide-cel, but we expect an approval decision by March 31, 2021, which is the time period specified within the CVR Agreement. **It is possible that COVID-19 could impact FDA operations such that the review of either or both of these CVR assets could be delayed.** Any delay in the timing of approval could reduce the resale price of the CVRs. If there is a significant delay that extends the FDA's review period beyond December 31, 2020 for liso-cel or March 31, 2021 for ide-cel, then no payment will be made under the CVRs and the CVRs will expire without value.

246. These statements were false and misleading because they omitted that (i) Bristol was slow-rolling the FDA application process for Liso-cel and Ide-cel in various ways so that it would miss at least one FDA milestone and avoid making the $6.4 billion CVR payment; (ii) Bristol had submitted a deliberately or recklessly insufficient BLA so as to require supplemental information in the form of an amendment, which caused the three-month postponement of the target approval date; (iii) Bristol was deliberately or recklessly not preparing adequately for inspections of its two Liso-cel manufacturing facilities, despite now having several additional months to do so as a result of the Major Amendment; (iv) Bristol had also submitted a BLA for Ide-cel that was intentionally or recklessly incomplete on its face; and (v) the effect of COVID-19 on the FDA approval process for Liso-cel paled in comparison to the delays created by Bristol's own actions. The effect of these omissions – especially in light of Defendants' contemporaneous Class Period statements about how Bristol was on track and trying to achieve FDA approval before the Milestones – was to lead reasonable investors to believe that COVID-19 was the one major risk for delay, as opposed to Bristol's own deliberate or reckless efforts to delay the approval process.

7. May 7, 2020, Earnings Call

247. On May 7, 2020, during an earnings call, Defendant Hirawat made statements about

how Bristol was committed to—and confident of—receiving approval of Liso-cel in advance of the CVR Milestone:

> Thank you, Nadim, and thanks, Terence for the question. As it relates to liso-cel, as you know that we had submitted the application with comprehensive datasets at the end of last year and the FDA accepted the Application for liso-cel and granted a priority review in February of this year. It now is just typical for the FDA to request additional information as they continue their review process, and after the company supplied information in response to several requests that the FDA has made, **FDA has decided that the information they have received constitute a major amendment, and that's why the PDUFA date has been extended by 3 months to 16th of November now.** ***And we are obviously committed to ensuring this medicine is available to patients as soon as possible, and we continue to meet our CVR milestones.*** Obviously we're not going to comment on the specifics of our regulatory discussions, but let me just remind that we remain very confident about the data for liso-cel for these patients with large B-cell lymphoma as it is an unmet medical need, and ***we are truly looking forward to get approval of this therapy towards the end of the year.*** Thank you. . . .
>
> For liso-cel, what we have said is that we remain confident in the data, we remain confident in the data that we submitted to the FDA. **It is very normal for the FDA to, as they review the file, to ask questions.** ***Certainly, we are looking towards the approval date now to end November.***
>
> During the review process, there may be many more questions that come to us. But that's a very normal process. So I think that's the way to look at it. I obviously cannot comment specifically on types of questions or one that relates to from a regulatory point of view. ***We remain confident and we are looking forward to bringing this treatment to patients as soon as possible towards the end of this year.***

248. These statements were false and misleading because they omitted that: (i) Bristol was slow-rolling the FDA application process for Liso-cel and Ide-cel in various ways so that it would miss at least one FDA milestone and avoid making the $6.4 billion CVR payment; (ii) Bristol had submitted a deliberately or recklessly insufficient BLA so as to require supplemental information in the form of an amendment, which caused the three-month postponement of the target approval date, (iii) Bristol was deliberately or recklessly not preparing adequately for

inspections of its two Liso-cel manufacturing facilities, despite now having several additional months to do so as a result of the major amendment; and (iv) Bristol had also submitted a BLA for Ide-cel that was intentionally or recklessly incomplete on its face.

8. May 19, 2020, UBS Virtual Global Healthcare Conference Presentation

249. On May 19, 2020, during a presentation at the UBS Virtual Global Healthcare Conference, Defendant Hirawat stated that "***we look towards hopefully approval of liso-cel towards the end of this year and we continue to go forward***."

250. These statements were false and misleading because they omitted that: (i) Bristol was slow-rolling the FDA application process for Liso-cel and Ide-cel in various ways so that it would miss at least one FDA milestone and avoid making the $6.4 billion CVR payment; (ii) Bristol had submitted a deliberately or recklessly insufficient BLA so as to require supplemental information in the form of an amendment, which caused the three-month postponement of the target approval date, (iii) Bristol was deliberately or recklessly not preparing adequately for inspections of its two Liso-cel manufacturing facilities, despite now having several additional months to do so as a result of the major amendment; and (iv) Bristol had also submitted a BLA for Ide-cel that was intentionally or recklessly incomplete on its face.

9. June 25, 2020, Investor Day Series Presentation

251. On June 25, 2020, during a presentation as part of Bristol's Investor Day Series, Defendant Hirawat made statements portraying the deficiencies in the CMC portion of the BLA for Liso-cel as unintentional and indicating that Bristol intended to achieve approval by the new target date of November 16, 2020:

> Liso-cel has a best-in-class CD19 targeting profile with the high affinity and differentiated safety. **We look forward to bring this call to patients soon because we have a PDUFA date of November 16 this year**. . . .

> Maybe I can start off and certainly then either Giovanni or Rupert, others can chime in. From the refusal to file perspective, certainly, every time we get a discussion with the agency or hear back from the agency, we learn the nuances. **So what we learned, as we said on the call, around the refusal to file, there were a lot many more questions around the data required in the filing from a CMC perspective.** So those are the learnings from there that we will be implementing in our future filings that we provide a more comprehensive view on the protocols utilized from a CMC perspective as well as on the data that we are providing in cell summaries to the -- to a larger format, so to say, in the module three. And then, of course, even during the review process, when we get information requests from the agency, we continue to improve on those as well in our subsequent filings so that we don't have repetition of the similar questions for every file. So a good question from you and certainly a learning for us as we continue to evolve. Let me start off and tee off the CVR question. And then certainly, either Giovanni or others can chime in on that. If you recall, the questions around ozanimod were related to certain data that were certainly -- that required a little bit more work to be done in terms of the pharmacology and/or clinical pharmacology, et cetera. So that was one aspect of it**. For liso-cel, there are specific questions that were asked that required for us to provide more data that were considered to be large enough that the agency needed to do the scientific review of it and extended the time line through a major amendment.** And the third case for ide-cel, basically, there was a lot more data that was required instead of the summary reports we had included in the file. So there are, I think, different issues. But overall, if you think about it, Celgene has had a huge and long history of filing and getting products approved, whether it be Reblozyl, Inrebic, Revlimid, pomalidomide and so on and so forth, or OTEZLA in the old days. So it is not that is an issue with the Celgene regulatory process. And by the way, some of these products have been filed when the companies became one as Celgene plus BMS or total BMS. So we all collectively contribute to the learning and contribute to this filing, and so I don't think it is an issue of a singular company having an issue with the regulatory part of it. Hopefully, that answers your question. Thank you.

252. Defendant Caforio then reiterated that they felt confident about achieving approval in time for the CVR Milestone, stating that "**we feel really good about where we are from a regulatory perspective. So that applies to products that may be included in the CVR** as well as the rest of the portfolio."

253. These statements were false and misleading because they omitted that: (i) Bristol was slow-rolling the FDA application process for Liso-cel and Ide-cel in various ways so that it

would miss at least one FDA milestone and avoid making the $6.4 billion CVR payment; (ii) Bristol had submitted a deliberately or recklessly insufficient BLA so as to require supplemental information in the form of an amendment, which caused the three-month postponement of the target approval date, (iii) Bristol was deliberately or recklessly not preparing adequately for inspections of its two Liso-cel manufacturing facilities, despite now having several additional months to do so as a result of the major amendment; and (iv) Bristol had also submitted a BLA for Ide-cel that was intentionally or recklessly incomplete on its face.

10. August 6, 2020, Form 10-Q

254. On August 6, 2020, Bristol filed a Form 10-Q with the SEC, signed by Defendant Caforio, stating again that the FDA had extended the target approval date, but citing COVID-19 as a possible cause of delay in the approval of Liso-cel:

> Announced that **the FDA has extended the action date by three months for the liso-cel BLA for the treatment of adults with relapsed or refractory large B-cell lymphoma after at least two prior therapies. The new PDUFA date is November 16, 2020**. . .
>
> **It is possible that the COVID-19 pandemic could delay the timing of the FDA's approval decisions for liso-cel and ide-cel, which could have a material adverse effect on our contingent value rights (CVRs).**
>
> We have submitted BLAs for liso-cel and ide-cel, the two remaining assets underlying our CVRs (the third CVR asset, Zeposia (ozanimod), was approved earlier this year). **These applications are under review by the FDA. Liso-cel has a PDUFA date of November 16, 2020.** We do not yet have a PDUFA date for ide-cel, but we continue to expect an approval decision by March 31, 2021, which is the time period specified within the CVR Agreement. **It is possible that COVID-19 could impact FDA operations, including the ability for the FDA to conduct on-site inspections, such that the review of either or both of these CVR assets could be delayed.** Any delay in the timing of approval could reduce the resale price of the CVRs. If there is a significant delay that extends the FDA's review period beyond December 31, 2020 for liso-cel or March 31, 2021 for ide-cel, then no payment will be made under the CVRs and the CVRs will expire without value.

255. These statements were false and misleading because they omitted that: (i) Bristol

was slow-rolling the FDA application process for Liso-cel and Ide-cel in various ways so that it would miss at least one FDA milestone and avoid making the $6.4 billion CVR payment; (ii) Bristol had submitted a deliberately or recklessly insufficient BLA so as to require supplemental information in the form of an amendment, which caused the three-month postponement of the target approval date, (iii) Bristol was deliberately or recklessly not preparing adequately for inspections of its two Liso-cel manufacturing facilities, despite now having several additional months to do so as a result of the major amendment; and (iv) Bristol had also submitted a BLA for Ide-cel that was intentionally or recklessly incomplete on its face. The effect of these omissions – especially in light of Defendants' contemporaneous Class-Period statements about how Bristol was on track and trying to achieve FDA approval before the Milestones – was to lead reasonable investors to believe that COVID-19 was the one major risk for delay, as opposed to Bristol's own deliberate or reckless efforts to delay the approval process.

11. August 6, 2020, Earnings Call

256. On an August 6, 2020 earnings call, Defendant Caforio stated that "in the very near term, **we are looking forward to the U.S. PDUFA dates for CC-486 in September and Liso-cel in November**. And of course beyond our new launches, we have a pipeline full of promise." These statements were false and misleading because they omitted that: (i) Bristol was slow-rolling the FDA application process for Liso-cel and Ide-cel in various ways so that it would miss at least one FDA milestone and avoid making the $6.4 billion CVR payment; (ii) Bristol had submitted a deliberately or recklessly insufficient BLA so as to require supplemental information in the form of an amendment, which caused the three-month postponement of the target approval date, (iii) Bristol was deliberately or recklessly not preparing adequately for inspections of its two Liso-cel manufacturing facilities, despite now having several additional months to do so as a result of the major amendment; and (iv) Bristol had also submitted a BLA for Ide-cel that was intentionally or

recklessly incomplete on its face.

12. September 8, 2020, Citibank 15th Annual BioPharma Conference Presentation

257. On September 8, 2020, during a presentation at Citibank's 15th Annual BioPharma Conference, Defendant Hirawat made statements about Bristol's commitment to achieving approval of Liso-cel and about the necessary site inspection:

> Samit Hirawat, Chief Medical Officer and Head of Global Drug Development:
> [W]e do believe that differentiation and the profile of liso-cel compared with many of the competitive products is very, very clear. I think it is well understood also by the health authorities, and thus far our discussions with the FDA. We are very encouraged by the way they've looked at it. So that is all going in a good direction. As you very well mentioned in the 10-Q, we have certainly disclosed that the site inspection for the cell therapy facilities has not been completed. And certainly with the evolution of the COVID-19, as well as the challenges it has posed, both for us and for the FDA, it does pose a risk because the FDA staff, like many of us, are operating under those significant constraints on travel because of COVID. Now with that said, while we typically don't provide any details on regulatory discussions, what I can say today is the FDA has informed us that they will require inspection of both our facilities in Washington State as well as the manufacturing organization for the vector, which is located in Texas. These inspections have not yet taken place. We are working very closely with the FDA to keep this application on track. **And as you know, the PDUFA date is in November, we still have some time to go. But at the same time, we are aware that some of the people -- same people who are at the FDA who will be working or working right now on liso-cel, will also be pulled into the inspection related activities that might be coming along for the COVID-related vaccines.** Now FDA is very well aware of that. They are juggling multiple things. As this is a public health crisis and they need to manage, as well as the diseases that are life-threatening, they also need to manage that. So those are all running in parallel. **I don't think we can say anything more except that the importance of this application is very, very high for us. I think it is also as important from the FDA perspective.** ***And we will continue to work closely with them, so that we can bring this product to the patients as soon as possible.***

258. These statements were false and misleading because they omitted that (i) Bristol was slow-rolling the FDA application process for Liso-cel and Ide-cel in various ways so that it

would miss at least one FDA milestone and avoid making the $6.4 billion CVR payment; (ii) Bristol had submitted a deliberately or recklessly insufficient BLA so as to require supplemental information in the form of an amendment, which caused the three-month postponement of the target approval date, (iii) Bristol was deliberately or recklessly not preparing adequately for inspections of its two Liso-cel manufacturing facilities, despite now having several additional months to do so as a result of the major amendment; (iv) Bristol had also submitted a BLA for Ide-cel that was intentionally or recklessly incomplete on its face, and (v) the effect of COVID-19 on the approval process, if any, was minimal compared to these sources of delay deliberately or recklessly created by Bristol.

13. September 15, 2020, Panel Discussion

259. In a Zoom panel discussion hosted by Endpoints News on September 15, 2020, Hirawat was asked about Liso-cel and responded as follows:

> Drugs that have been granted breakthrough therapy designation, the agency, in general, and it's not about oncology, it's about anybody with a drug which has a high transformative potential, which has a breakthrough therapy designation, FDA always provides more chances for that dialogue, and we had that chances as well. So we have a continuous dialogue with the FDA, and FDA has provided us the good guidance, and we continue to work. **Our PDUFA date, everybody knows, is in November, so we'll just keep on that.**

260. These statements were false and misleading because they omitted that (i) Bristol was slow-rolling the FDA application process for Liso-cel and Ide-cel in various ways so that it would miss at least one FDA milestone and avoid making the $6.4 billion CVR payment; (ii) Bristol had submitted a deliberately or recklessly insufficient BLA so as to require supplemental information in the form of an amendment, which caused the three-month postponement of the target approval date, (iii) Bristol was deliberately or recklessly not preparing adequately for inspections of its two Liso-cel manufacturing facilities, despite now having several additional

months to do so as a result of the major amendment; (iv) Bristol had also submitted a BLA for Ide-cel that was intentionally or recklessly incomplete on its face; and (v) the effect of COVID-19 on the approval process, if any, was minimal compared to these sources of delay deliberately or recklessly created by Bristol.

14. September 17, 2020, Morgan Stanley 18th Annual Global Health Care Conference Presentation

261. On September 17, 2020, during a presentation at Morgan Stanley's 18th Annual Global Healthcare Conference, Defendant Caforio responded to a question about the timing of the Liso-cel facilities inspections by blaming the COVID-19 pandemic for jeopardizing timely approval by the FDA by delaying site inspections:

> David Risinger, Analyst:
>
> Got it. So, that just -- yeah since you mentioned about the uncertain COVID environment, I just hinted that quickly with a question before then returning to your TYK2. The FDA seems to be focusing most of its attention on COVID vaccines and therapeutics. Is there any indication from the FDA that it will be able to inspect the two liso-cel facilities in coming weeks?
>
> Giovanni Caforio, Chief Executive Officer and Chairman of the Board:
>
> Yeah, Dave, thank you for the question. So this is obviously a very important filing for us and as you know, we made a number of comments in our quarterly disclosures and at a meeting last week. **I would say the overall process with the FDA is going well. At the same time, as we mentioned last week, the FDA has informed us that they will want to inspect, they will need to inspect both of our work plans during the review process** and when we presented last week, those inspections had clearly not yet occurred. So obviously **there's the COVID and the complexity of travel during this time and I would say that is a main concern, somewhat increases the risk to the process.** I don't think there's much I can add at this point. I can tell you ***we're working very actively with the FDA to keep the review and the inspection process moving because we want to get the product to patients as soon as possible*** and we've updated the market last week and there's nothing I can add at this point.

262. These statements were false and misleading because they omitted that: (i) Bristol was slow-rolling the FDA application process for Liso-cel and Ide-cel in various ways so that it

would miss at least one FDA milestone and avoid making the $6.4 billion CVR payment; (ii) Bristol had submitted a deliberately or recklessly insufficient BLA so as to require supplemental information in the form of an amendment, which caused the three-month postponement of the target approval date, (iii) Bristol was deliberately or recklessly not preparing adequately for inspections of its two Liso-cel manufacturing facilities, despite now having several additional months to do so as a result of the major amendment; (iv) Bristol had also submitted a BLA for Ide-cel that was intentionally or recklessly incomplete on its face, and (v) the effect of COVID-19 on the approval process, if any, was minimal compared to these sources of delay deliberately or recklessly created by Bristol. The effect of these omissions – especially in light Defendants' Class Period statements about how Bristol was on track and trying to achieve FDA approval before the Milestones – was to lead reasonable investors to believe that COVID-19 was the one major risk for delay, as opposed to Bristol's own deliberate or reckless efforts to delay the approval process.

15. September 21, 2020, Investor Event at European Society of Medical Oncology

263. On September 21, 2020, Defendant Hirawat participated in an investor event at the European Society of Medical Oncology, at which he stated that with respect to Liso-cel, "we continue to work with the FDA in terms of assessing when the inspections will be. These plants have not yet been inspected. Just a reminder, we do have a breakthrough therapy designation. I remind you that we have a PDUFA date in November. As soon as the FDA will inform us, we'll certainly take that into account. But right now, we don't have a date for inspection at the time, and so they have not been inspected yet."

264. This statement was false and misleading because it omitted that (i) Bristol was slow-rolling the FDA application process for Liso-cel in various ways so that it would miss at least one FDA milestone and avoid making the $6.4 billion CVR payment; (ii) Bristol had submitted a

deliberately or recklessly insufficient BLA so as to require supplemental information in the form of an amendment, which caused the three-month postponement of the target approval date to November 17, 2020, and (iii) Bristol was deliberately or recklessly not preparing adequately for inspections of its two Liso-cel manufacturing facilities, despite now having several additional months to do so as a result of the major amendment.

16. September 24, 2020, Interview with Scrip Pharma Intelligence

265. On September 24, 2020, *Scrip Pharma Intelligence* published an article concerning a then-recent interview with Defendant Hirawat, during which Hirawat noted that "**at this time, the liso-cel and ide-cel programs are on track to meet their approval goals.**"

266. This statement was false and misleading because it omitted that (i) Bristol was slow-rolling the FDA application process for Liso-cel and Ide-cel in various ways so that it would miss at least one FDA milestone and avoid making the $6.4 billion CVR payment; (ii) Bristol had submitted a deliberately or recklessly insufficient BLA so as to require supplemental information in the form of an amendment, which caused the three-month postponement of the target approval date to November 17, 2020, (iii) Bristol was deliberately or recklessly not preparing adequately for inspections of its two Liso-cel manufacturing facilities, despite now having several additional months to do so as a result of the major amendment; (iv) Bristol had also submitted a BLA for Ide-cel that was intentionally or recklessly incomplete on its face.

17. September 30, 2020, Statement before the Committee on Oversight and Reform of the U.S. House of Representatives

267. On September 30, 2020, Defendant Caforio made a statement before the Committee on Oversight and Reform of the U.S. House of Representatives concerning "Bristol Myers Squibb, our acquisition of Celgene Corporation, and our focus on developing the next generation of therapies for patients' unmet medical needs," as well as the COVID-19 pandemic. In his statement,

Defendant Caforio said, "**the FDA has accepted our submissions for liso-cel and ide-cel this year, and granted priority review for both.**"

268. This statement was false and misleading because it omitted that: (i) on May 5, 2020, the FDA had issued a Major Amendment Acknowledgment, which automatically extended the PDUFA target approval deadline from August 17, 2020 to November 17, 2020, rendering Liso-cel's "Priority Review" designation less meaningful; and (ii) Bristol was slow-rolling the FDA application process for Liso-cel and Ide-cel in various ways so that it would miss at least one FDA milestone and avoid making the $6.4 billion CVR payment.

18. November 5, 2020, Form 10-Q

269. On November 5, 2020, another part of Bristol's fraud was revealed. Specifically, Bristol filed a Form 10-Q with the SEC, signed by Caforio, which revealed that one of the necessary site inspections had not even been scheduled. This constituted a partial disclosure or materialization of risk of the fraud, as the delay was the direct result of deliberate or reckless actions by Bristol to delay the FDA approval process that Defendants had concealed in their prior statements:

> Contingent Value Right Update
>
> We have filed BLAs for liso-cel and ide-cel, the two remaining assets underlying the CVRs that we issued in connection with the Celgene transaction that have not been approved by the FDA. The applications are under review by the FDA. The third CVR asset, Zeposia, was approved earlier this year. Liso-cel has a PDUFA date of November 16, 2020 and ide-cel has a PDUFA date of March 27, 2021. Unless the FDA approves liso-cel for the treatment of relapsed-refractory diffuse large B cell lymphoma in humans by December 31, 2020 and ide-cel for the treatment of relapsed/refractory multiple myeloma in human by March 31, 2021, no payment will be made under the CVRs and the CVRs will expire valueless. **The FDA has informed us that inspections of two manufacturing facilities are required before they can issue a decision on the liso-cel application. One of those inspections has occurred; the other has not yet been scheduled. We do not believe that the scheduling of the second site inspection is dependent on the outcome of the first site's inspection, as they are independent facilities.**

270. However, in the same Form 10-Q, Defendants falsely claimed that the delays were out of their control and the result of the COVID-19 pandemic, concealing Bristol's own continuing role in causing delay:

> **It is possible that the COVID-19 pandemic could delay the timing of the FDA's approval decisions for liso-cel and ide-cel, which could have a material adverse effect on the CVRs that we issued in connection with the Celgene transaction."**
>
> * * *
>
> ***It is possible that the COVID-19 pandemic could delay the timing of the FDA's approval decisions for liso-cel and ide-cel, which could have a material adverse effect on the CVRs that we issued in connection with the Celgene transaction.***
>
> *We have submitted BLAs for liso-cel and ide-cel, the two remaining assets underlying the CVRs that we issued in connection with the Celgene transaction (the third CVR asset, Zeposia (ozanimod), was approved earlier this year). These applications are under review by the FDA. Liso-cel has a PDUFA date of November 16, 2020 and ide-cel has a PDUFA date of March 27, 2021.* ***It is possible that COVID-19 could impact FDA operations, including the ability for the FDA to conduct on-site inspections, such that the review of either or both of these CVR assets could be delayed.*** *Any delay in the timing of approval could reduce the resale price of the CVRs. If there is a significant delay that extends the FDA's review period beyond December 31, 2020 for liso-cel or March 31, 2021 for ide-cel, then no payment will be made under the CVRs and the CVRs will expire without value.*

271. These statements were false and misleading because they omitted that: (i) Bristol was slow-rolling the FDA application process for Liso-cel and Ide-cel in various ways so that it would miss at least one FDA milestone and avoid making the $6.4 billion CVR payment; (ii) Bristol had submitted a deliberately or recklessly insufficient BLA so as to require supplemental information in the form of an amendment, which caused the three-month postponement of the target approval date; (iii) Bristol had deliberately or recklessly not prepared adequately for inspections of its two Liso-cel manufacturing facilities, despite now having several additional months to do so as a result of the major amendment; (iv) Bristol had already received from the

FDA Form 483 informing it of significant deficiencies in the Juno facility, and it was slow-walking an incomplete response to the FDA; (v) Bristol had also submitted a BLA for Ide-cel that was intentionally or recklessly incomplete on its face; and (vi) the effect of COVID-19 on the approval process, if any, was minimal compared to these sources of delay deliberately or recklessly created by Bristol. The effect of these omissions – especially in light of Defendants' Class Period statements about how Bristol was on track and trying to achieve FDA approval before the Milestones – was to lead reasonable investors to believe that COVID-19 was the one major risk for delay, as opposed to Bristol's own deliberate or reckless efforts to delay the approval process.

272. Despite Defendants' continued treatment of the COVID-19 pandemic as the cause of delay, by the close of the market on November 5, 2020, the value of the CVRs had dropped by 64% since closing the previous day—from $3.40 to $1.22 per share, with volume of more than 72 million shares.

19. November 5, 2020, Earnings Call

273. On the November 5, 2020, earnings call about the Company's third-quarter earnings, Bristol executives were asked for an update on the FDA's Liso-cel and Ide-cel review, to which Hirawat and Caforio responded as follows:

> Hirawat: From liso-cel perspective, **not much to share, except for the fact that we've already communicated, we continue our dialogue with the regulatory agencies.** We've had the inspection done for the facility in Washington. And as we have communicated earlier that we don't have any scheduled inspections for the second facility, which is one -- which is independent of the other facility.
>
> For liso-cel, we have a PDUFA date on 16th of November. For ide-cel, same thing, we are continuing our dialogue and that we have a PDUFA date of March 27 of 2021. That's where we are. I don't know, Nadim, if you want to add something, or Giovanni?
>
> Caforio: The only thing I would add is, just to close on what Samit mentioned **with respect to liso-cel, as always, obviously, we will update you as our discussion with the regulatory authorities progress.**

274. An analyst from Morgan Stanley followed up by asking, "So, I have two questions, please. First, could you provide more color on what you need to discuss with the FDA on liso-cel? It seemed to me that discussion should be over by this point. And a follow-on to that is, are there any issues with the recent manufacturing inspections, or do you have confidence following those manufacturing inspections?" Hirawat responded:

> For liso-cel, as we mentioned earlier, as we disclosed in the past, FDA has informed the Company that both our plants in Washington as well as the one in Texas, need to be inspected. They've been able to inspect our plants in Bothell, Washington at this time but have not scheduled any inspection of the second plant. As you know, they actually are doing what they can to ensure that the staffs are kept safe in this COVID pandemic. And because of the travel restrictions, we have to obviously honor their desire as to where they go and when they go. **As we've said in the past that the conversations with the agencies are going well, and we look forward to seeing the -- hopefully, the approval at some point to be able to bring to the patients as soon as possible.** We'll obviously let you know as soon as we get the decision. We are not going to comment obviously specifically about the dialogue around inspections, et cetera. We're generally very happy with the dialogue that has been happening.

275. These statements were false and misleading because they omitted that: (i) Bristol was slow-rolling the FDA application process for Liso-cel and Ide-cel in various ways so that it would miss at least one FDA milestone and avoid making the $6.4 billion CVR payment; (ii) Bristol had submitted a deliberately or recklessly insufficient BLA so as to require supplemental information in the form of an amendment, which caused the three-month postponement of the target approval date; (iii) Bristol had deliberately or recklessly not prepared adequately for inspections of its two Liso-cel manufacturing facilities, despite now having several additional months to do so as a result of the major amendment; (iv) Bristol had already received from the FDA Form 483 informing it of significant deficiencies in the Juno facility, and it was slow-walking an incomplete response to the FDA; (v) Bristol had also submitted a BLA for Ide-cel that was intentionally or recklessly incomplete on its face; and (vi) the effect of COVID-19 on the approval

process, if any, was minimal compared to these sources of delay deliberately or recklessly created by Bristol. The effect of these omissions – especially in light of Defendants' Class Period statements about how Bristol was on track and trying to achieve FDA approval before the Milestones – was to lead reasonable investors to believe that COVID-19 was the one major risk for delay, as opposed to Bristol's own deliberate or reckless efforts to delay the approval process.

20. November 16, 2020, Press Release

276. On November 16, 2020, Bristol issued a press release announcing that the FDA had delayed its inspection of the Lonza Facility. This constituted another partial corrective disclosure or materialization of risk, as the fact of this delay occurring so near the Milestone resulted from Defendants own efforts to delay the approval process, which they had concealed in their prior statements.

> The FDA was unable to conduct an inspection of a third-party manufacturing facility in Texas during the current review cycle due to travel restrictions related to the COVID-19 pandemic. Therefore, the FDA is deferring action on the application until the inspection can be completed. The application remains under review. The FDA did not provide a new anticipated action date.

277. However, this press release, with a quote from Defendant Hirawat, continued to falsely present Bristol as committed to achieving approval in time for the Milestones:

> **"Bristol Myers Squibb continues to work closely with the FDA to support the ongoing review of the BLA for liso-cel** said Samit Hirawat, M.D., executive vice president, chief medical officer, global drug development, Bristol Myers Squibb. "We are committed to bringing liso-cel to patients with relapsed or refractory large B-cell lymphoma who still have significant unmet need."
>
> * * *
>
> U.S. FDA approval of liso-cel by December 31, 2020 is one of the required remaining milestones of the Contingent Value Rights issued upon the close of the Celgene acquisition in the fourth quarter of 2019. The other is U.S. FDA approval of Idecabtagene Vicleucel (ide-cel) by March 31, 2021. ***The company is committed to working with the FDA to progress both***

applications to achieve the remaining regulatory milestones required by the CVR.

278. These statements were false and misleading because they omitted that: (i) Bristol was slow-rolling the FDA application process for Liso-cel and Ide-cel in various ways so that it would miss at least one FDA milestone and avoid making the $6.4 billion CVR payment; (ii) Bristol had submitted a deliberately or recklessly insufficient BLA so as to require supplemental information in the form of an amendment, which caused the three-month postponement of the target approval date; (iii) Bristol had deliberately or recklessly not prepared adequately for inspections of its two Liso-cel manufacturing facilities, despite now having several additional months to do so as a result of the major amendment; (iv) Bristol had slow-walked its response to a Form 483 for the Juno facility, and the response itself had been inadequate and would require supplemental submissions; (v) Bristol had also submitted a BLA for Ide-cel that was intentionally or recklessly incomplete on its face; and (vi) the effect of COVID-19 on the approval process, if any, was minimal compared to these reasons for delay deliberately or recklessly created by Bristol.

279. Despite Defendants' false reassurances, by the close of the market on November 16, 2020, the value of the CVRs had dropped by 42% since closing the previous day—from $1.40 to $0.80 per share, with volume of more than 38 million shares.

VI. ADDITIONAL SCIENTER ALLEGATIONS

280. The allegations in this section concern only the claims brought under Sections 10(b) and 20(a) of the Exchange Act—not the claims brought under Section 14(a) of the Exchange Act, which are brought under a negligence standard, or the claims brought under Sections 11, 12(a)(2), and 15 of the Securities Act, which are brought under a strict liability standard.

281. As alleged herein, Defendants acted with scienter when making the challenged false and misleading statements during the Class Period. Each Defendant knew or recklessly disregarded

that the public documents and statements issued or disseminated in the name of Bristol were materially false and misleading and omitted material information; knew or recklessly disregarded that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, Defendants, by virtue of their receipt of information reflecting the true facts regarding Bristol, their control over, and/or receipt and/or modification of Bristol's allegedly materially misleading misstatements and/or their associations with Bristol which made them privy to confidential proprietary information concerning Bristol, participated in the fraudulent scheme alleged herein.

282. As alleged herein, the executive Defendants Bristol, Caforio, and Hirawat specifically told investors that oversight of the CVR was a *Board* responsibility, assuring investors that Individual Defendants were closely following and influencing the approval process of CVR therapies. Moreover, as alleged herein, senior personnel at Bristol were intimately involved in overseeing the BLA and CMC application processes, as well as the inspections of the Lonza and Juno sites. Additionally, the corporate structure of Bristol – which included a Science & Technology Committee and an Integration Committee, specifically devoted to integrating Celgene's drug technologies into Bristol's infrastructure – served the direct purpose of ensuring FDA approval of Liso-cel.

283. Bristol made numerous blatantly deficient submissions to the FDA, a pattern that bespoke recklessness or a deliberate effort to delay the approval process. Bristol submitted a deficient CMC portion of the BLA for Liso-cel that required so much supplemental information as to lead to a Major Amendment, causing the target date to be pushed back by three months. ***After***

that occurred, Bristol then announced it submitted a BLA for Ide-cel with a CMC portion that was *incomplete on its face*, which received a Refuse to File letter from the FDA and pushed the approval date for Ide-cel up against the March 31, 2021, deadline.

284. Bristol's failure to prepare its inspection facilities – despite having several more months to do so as a result of the Major Amendment – also involved recklessness or deliberate conduct. Bristol chose to send small and inexperienced teams to the Lonza and Juno facilities to prepare them for inspections. For the Lonza facility, the team was led by an employee with no experience working on an FDA pre-approval inspection (let alone experience overseeing preparations for cell therapy or viral manufacturing inspection) – a shocking departure from normal industry practices.

285. The Form 483s for both facilities listed basic, easily avoidable deficiencies. According to the former employees who worked at those facilities, many of those deficiencies were also well known within the Company and elevated to management well in advance of the FDA audit.

286. After receiving the Form 483 for the Juno facility, Bristol waited 15 business days – the maximum allowed under FDA policy and several days more than is normal – to file its response. The FDA Biologics Expert said that this Form 483 response could have easily been filed within 10 calendar days.

287. Bristol's Form 483 responses for both the Juno and Lonza facilities were deficient and required supplementation – a very rare occurrence. Bristol waited until December 23, 2020 – just a week before the Milestone Deadline – to provide its last supplemental information to the FDA.

288. Liso-cel was eventually approved just 36 days after the Milestone, allowing the

Company to bring it to market quickly after avoiding the $6.4 billion payout. And Ide-cel was approved on March 26, 2021 – one small, deliberate delay away from missing its March 31, 2021 Milestone if such a delay had been necessary for avoiding the CVR payout.

289. A comparison of the Liso-cel approval timeline to other biologics makes it highly implausible that the extent of the delay was innocent. The approval for Liso-cel took nearly twice as long as for the three other CAR-T therapies approved in recent years, one of which was submitted for approval a week before Liso-cel and had a PDUFA date a week before Liso-cel's original PDUFA date but which received approval 189 days faster. The timeline for Liso-cel approval was also much longer than the timeline for approval of any other Celgene or Bristol biologic over the previous six years. And, according to the analysis of the FDA Biologics Expert, the eleven-month approval time for Liso-cel was statistically anomalous, even as compared with other drugs approved during COVID-19. *See supra* ¶¶ 203-05.

290. Bristol refused to buy back any CVRs on the open market, even when all three drugs were ostensibly on track for approval and the CVR was trading well below the $9.00 payout. Defendants gave the excuse that they might have asymmetrical information compared to other investors, yet this did not stop them from making numerous buybacks of Bristol common stock during the same time period.

291. Bristol also refused to alter or renegotiate the CVR deadlines in light of the COVID-19 pandemic. Not doing so provides further confirmation of Bristol's desire to never pay the CVR investors the $6.4 billion owed, and that COVID-19 was not to blame for the delay in FDA approval of Liso-cel.

292. Defendants tried to cover up their role in delaying the approval of Liso-cel. They blamed COVID-19, yet in 2020 the FDA approved 53 novel drugs, of which 20 were oncology

drugs, as well as 13 biologics (including Tecartus, the CAR-T therapy that had been put on a nearly identical approval timeline as Liso-cel but which was approved 189 days faster).

293. Defendants were also highly motivated to materially misrepresent their intention and actions relating to FDA approval of Liso-cel, because Bristol could avoid a payment of $6.4 billion to CVR holders if Bristol was seen as having made a diligent effort to obtain approval for Liso-cel by December 31, 2020. This was a substantial sum for the Company, which incurred a net *loss* of $9.0 billion in 2020 and made net earnings of $7.0 billion – barely more than the size of the CVR payout – in 2021. This directly affected the personal finances of the Individual Defendants because they held millions of dollars' worth of Bristol common stock and because their long-term incentive award depended on the performance of that stock

VII. LOSS CAUSATION – EXCHANGE ACT CLAIMS

294. As described herein, Defendants made materially false and misleading statements and omissions of material facts in the Joint Proxy. These statements caused Plaintiffs and other members of the Class to accept Merger consideration that failed to adequately value Celgene's shares. As a result of their possession and exchange of Celgene common stock in the Merger, Plaintiffs and other Class members suffered an economic loss.

295. During the Class Period, Defendants continued to make false and misleading statements that inflated the price of the CVRs and operated as a deceit on purchasers and acquirers of those CVRs. As detailed above, throughout the Class Period, Defendants represented that Bristol was diligently working toward FDA approval of Liso-cel before the CVR Milestone of December 31, 2020, despite Defendants' knowing that Bristol was intentionally or recklessly delaying the approval process so that approval would come after the Milestone.

296. As various delays in the approval process were announced during the Class Period,

the artificial inflation slowly dissipated.

297. On May 6, 2020, the price of CVRs declined by 15% from the prior day, from $4.43 to $3.75 per share, in response to the press release in which Bristol announced that the FDA's target approval date for Liso-cel had been pushed back from August 17 to November 16, 2020.

298. On September 8, 2020, the price of CVRs declined by 15%, from an opening price of $2.80 per share to a closing price of 2.30 per share, in response to Bristol's disclosure that the Lonza facility would require an inspection and that neither of the two required plant inspections had occurred yet.

299. On November 5, 2020, the price of CVRs declined by 64% from the prior day, from $3.40 to $1.22 per share, in response to statements by Bristol in its Form 10-Q revealing that only one of its Liso-cel facilities has been inspected and that the other facility's inspection had yet to be scheduled.

300. On November 16, 2020, the price declined further, from $1.40 to $0.80 per share, in response to the passing of the FDA's target date and Bristol's announcement that the inspection of the Lonza Facility had been further delayed.

301. When the December 31, 2020 CVR Milestone for Liso-cel passed without Bristol having obtained FDA approval for Liso-cel, the remaining artificial inflation dissipated and the CVRs lost all remaining value.

302. The declines in the value of the CVRs in response to delays in the approval process—and in response the passing of the CVR Milestone for Liso-cel approval on December 31, 2020—were the direct result of Defendants' fraudulent misrepresentations and omissions, which had concealed Bristol's deliberate or reckless efforts to delay the process and had led investors to believe that Bristol was making a diligent effort to achieve approval by the time of the

Milestone. Thus, the economic loss, *i.e.*, damages, suffered by Plaintiffs and the other Class members was a direct result of Defendants' scheme to deceive investors while deliberately ensuring that Bristol would not have to pay out the $6.4 billion for the CVRs.

VIII. PRESUMPTION OF RELIANCE

303. Class members who purchased the CVRs during the Class Period did so in reliance on Defendants' false and misleading statements.

304. At all relevant times, the market for the CVRs was an efficient market for the following reasons, among others:

a) The CVRs met the requirements for listing and were listed and actively traded on the New York Stock Exchange, a highly efficient and automated market.

b) Bristol communicated with public investors via established market communication mechanisms, including filings with the SEC and dissemination of press releases on the national circuits of major newswire services and other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services;

c) Bristol was followed by numerous newspapers and several securities analysts employed by major brokerage firms who wrote reports that were distributed to the sales force and certain customers of their respective brokerage firms during the Class Period. Each of these reports was publicly available and entered the public marketplace; and

d) Unexpected material news about Bristol was reflected in and incorporated into the price of CVRs during the Class Period.

305. As a result of the foregoing, the market for the CVRs promptly digested current information from all publicly available sources and reflected such information in the CVRs' price. Under these circumstances, all purchasers of the CVRs during the Class Period suffered similar

injury through their purchase of the CVRs at artificially inflated prices, and a presumption of reliance applies.

306. Alternatively, reliance need not be proven in this action because the action involves omissions and deficient disclosures. Positive proof of reliance is not a prerequisite to recovery pursuant to ruling of the United States Supreme Court in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972). All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered the omitted information important in deciding whether to buy or sell the subject security.

IX. CLASS ACTION ALLEGATIONS

307. Plaintiffs bring this action on behalf of all persons or entities who purchased or otherwise acquired CVRs during the Class Period and were damaged thereby.

308. The Class is so numerous that joinder of all members is impracticable. As of the close of business on the Merger record date — March 1, 2019 — approximately 702,450,444 shares of Celgene common stock were outstanding and entitled to vote on the Merger. Throughout the Class Period, more than 715 million CVRs were outstanding and trading on the NYSE. Those shares were held by hundreds, if not thousands, of individuals and entities located throughout the country.

309. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class which predominate over questions which may affect individual Class members include:

(a) Whether the federal securities laws were violated by Defendants' conduct as alleged herein;

(b) Whether the Registration Statement, Joint Proxy, and other public statements disseminated to the investing public during the Class Period contained material

misstatements or omitted to state material information;

(c) Whether and to what extent the market prices of CVRs were artificially inflated and/or distorted during the Class Period due to the non-disclosures and/or misstatements complained herein;

(d) Whether, solely with respect to the claims under Section 10(b) and 20(a) of the Exchange Act, Defendants acted with scienter;

(e) Whether, solely with respect to the claims under Section 10(b) and 20(a) of the Exchange Act, reliance may be presumed;

(f) Whether Bristol was a seller under Section 12(a)(2) of the Securities Act;

(g) Whether Plaintiffs are entitled to rescission; and

(h) Whether the members of the Class have sustained damages as a result of the conduct complained of herein, and if so, the proper measure of damages.

310. Plaintiffs' claims are typical of those of the Class because Plaintiffs and the other members of the Class sustained damages from Defendants' wrongful conduct.

311. Plaintiffs will adequately protect the interests of the Class and have retained counsel experienced in class action securities litigation. Plaintiffs have no interests which conflict with those of the Class.

312. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

X. INAPPLICABILITY OF STATUTORY SAFE HARBOR

313. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pled in this Complaint. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false may be characterized as

forward-looking, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Further, to the extent that the statutory safe harbor is determined to apply to any forward-looking statements pled herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements were made, the speaker had actual knowledge that the forward-looking statement was materially false or misleading and/or the forward-looking statement was authorized or approved by an executive officer of Bristol who knew that the statement was false when made.

XI. STATUTE OF LIMITATIONS

314. Plaintiffs could not have learned about Bristol's false statements in the Registration Statement and Joint Proxy and during the Class Period until the CVR Agreement terminated and Bristol failed to achieve the Milestone on December 31, 2020 at the earliest. The Complaint in this action was filed within one year of the discovery of the facts constituting the claim. Plaintiffs' claims are, therefore, brought within the applicable statute of limitations.

COUNT I

On Behalf of Plaintiffs and the Class Against Defendants Bristol, Caforio, and Hirawat ("Section 10(b) Defendants") for Violations of Section 10(b) of the Exchange Act

315. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

316. During the Class Period, the Section 10(b) Defendants disseminated or approved the materially false and misleading statements and omissions specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

317. The Section 10(b) Defendants:

a) employed devices, schemes, and artifices to defraud;

b) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and

c) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers or acquirers of the CVRs during the Class Period.

318. Plaintiffs and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for the CVRs. Plaintiffs and the Class would not have acquired or purchased the CVRs at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by the Section 10(b) Defendants' misleading statements or omissions.

319. As a direct and proximate result of the Section 10(b) Defendants' wrongful conduct, Plaintiffs and other members of the Class suffered damages in connection with their purchases and acquisitions of the CVRs during the Class Period.

COUNT II

On Behalf of Plaintiffs and the Class Against Defendants Bristol, Caforio, Sato, Arduini, Bertolini, Emmens, Grobstein, Lacy, Paliwal, Samuels, Storch, and Vousden ("Section 14(a) Defendants") for Violations of Section 14(a) of the Exchange Act and Rule 14a-9 Promulgated Thereunder

320. Plaintiffs incorporate each and every allegation set forth above as if fully set forth herein, except that for purposes of this claim, Plaintiffs expressly exclude and disclaim any allegation that could be construed as alleging or sounding in fraud or intentional or reckless misconduct. This claim is based solely on negligence.

321. The Section 14(a) Defendants solicited investors through dissemination of a materially false and misleading Joint Proxy containing statements that, in violation of Section

14(a) of the Exchange Act and Rule 14a-9, and in light of the circumstances under which they were made, misrepresented or omitted material facts necessary to make the statements therein not materially false or misleading.

322. The Section 14(a) Defendants were at least negligent in issuing a false and misleading Joint Proxy. Plaintiffs, while reserving all rights, expressly disclaim and disavow at this time any allegation in this Complaint that could be construed as alleging fraud against the Section 14(a) Defendants in connection with this Count. This claim sounds in negligence based on the failure of the Section 14(a) Defendants to exercise reasonable care to ensure the Joint Proxy did not contain the material misstatements and omissions alleged herein.

323. The Proxy was prepared, reviewed and/or disseminated on behalf of the Section 14(a) Defendants. By virtue of their positions within Bristol, the Section 14(a) Defendants were aware of this information and their duty to disclose this information in the Joint Proxy.

324. The omissions and false and misleading statements in the Joint Proxy are material in that a reasonable shareholder would have considered them important in deciding how to vote on the Merger. In addition, a reasonable investor would view a full and accurate disclosure as significantly altering the total mix of information made available in the Joint Proxy and in other information reasonably available to Celgene shareholders.

325. As a result of the material misstatements and omissions, Celgene shareholders voted in favor of the Merger.

38. The Joint Proxy was an essential link in causing Celgene shareholders to approve the Merger.

COUNT III

On Behalf of Plaintiffs and the Class Against Defendants Caforio, Sato, Arduini, Bertolini, Emmens, Grobstein, Lacy, Paliwal, Samuels, Storch, Vousden, and Hirawat for Violations of Section 20(a) of the Exchange Act

326. Plaintiffs incorporate each and every allegation set forth above as if fully set forth herein.

327. The Section 14(a) Individual Defendants disseminated a false and misleading Joint Proxy in violation of Section 14(a) of the Exchange Act and Rule 14a-9, promulgated thereunder. The Section 10(b) Individual Defendants also made false and misleading statements or omitted material information and engaged in a scheme that operated as a fraud and deceit throughout the Class Period in violation of Section 10(b) of the Exchange Act and Rule 10b-5, promulgated thereunder.

328. The Section 14(a) Individual Defendants and the Section 10(b) Individual Defendants acted as controlling persons of Bristol within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their positions and culpable participation in and/or awareness of Bristol's operations and/or intimate knowledge of the false and misleading statements made during the Class Period and contained in the Joint Proxy filed with the SEC, the Section 14(a) Individual Defendants and the Section 10(b) Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of Bristol, including the content and dissemination of the various statements during the Class Period and in the Joint Proxy that Plaintiff contends are false and misleading.

329. The Section 14(a) Individual Defendants were provided with or had unlimited access to copies of the Joint Proxy, and Section 10(b) Individual Defendants were provided with or had unlimited access to other statements alleged by Plaintiffs to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

330. In particular, these Individual Defendants had direct and supervisory involvement

in the day-to-day operations of Bristol, and, therefore, are presumed to have had the power to control or influence the particular transactions giving rise to the Exchange Act violations alleged herein, and exercised the same. In regard to the Joint Proxy, the misrepresented information identified above was reviewed by the Section 14(a) Individual Defendants prior to the shareholder vote on the Merger. The Joint Proxy at issue contains the unanimous recommendation of the Section 14(a) Individual Defendants to approve the Merger and the Joint Proxy was issued on behalf of each of them. They were thus directly involved in the making of the Joint Proxy.

331. By virtue of the foregoing, the Section 14(a) Individual Defendants and the Section 10(b) Individual Defendants have violated Section 20(a) of the Exchange Act.

332. As set forth above, the Section 14(a) Individual Defendants and the Section 10(b) Individual Defendants had the ability to exercise control over and did control a person or persons who have each violated Sections 10(b) and 14(a) of the Exchange Act and Rule 10b-5 and 14a-9, by their acts and omissions as alleged herein. By virtue of their positions as controlling persons, the Section 14(a) Individual Defendants and the Section 10(b) Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of those Defendants' conduct, Plaintiffs and the Class were irreparably harmed.

COUNT IV

On Behalf of Plaintiffs and the Class Against Defendants Bristol, Caforio, Sato, Arduini, Bancroft, Santiago, Bertolini, Emmens, Grobstein, Lacy, Paliwal, Samuels, Storch, and Vousden ("Section 11 Defendants") Violations of Section 11 of the Securities Act

333. Plaintiffs incorporate each and every allegation set forth above as if fully set forth herein, except that for purposes of this claim, Plaintiffs expressly exclude and disclaim any allegation that could be construed as alleging or sounding in fraud or intentional or reckless misconduct. This claim is based solely on strict liability.

334. This count is brought pursuant to Section 11 of the Securities Act, 15 U.S.C. §77k,

on behalf of Plaintiffs and the other members of the Class, against the Section 11 Defendants for issuing the Registration Statement that omitted or contained false and misleading information as described herein. Section 11 makes the issuer of securities pursuant to a registration statement absolutely liable for damages as defined therein where such registration statement contained an untrue statement of material fact or omitted to state a material fact required to be stated therein or necessary to make the statements therein no misleading. This count is not alleging fraud or intentional conduct or recklessness.

335. Plaintiffs and the other members of the Class acquired the CVRs issued pursuant to the Registration Statement.

336. Bristol is the registrant for the CVRs offered in the Registration Statement. As issuer of the securities, Bristol is strictly liable to Plaintiffs and the Class for the misstatements and omissions contained in the Registration Statement.

39. At the time of each offering, the Registration Statement for the offering contained untrue statements of material fact, omitted to state facts necessary to make the statements made therein not misleading, and failed to disclose required material information.

337. Bristol is strictly liable pursuant to Section 11 of the Securities Act for any material misstatements of fact or failure to disclose facts necessary to make the statements made in the Registration Statement not materially misleading.

338. In connection with the offering, Bristol used the means and instrumentalities of interstate commerce and the United States mails.

339. By reasons of the conduct herein alleged, Bristol and the Section 11 Defendants violated Section 11 of the Securities Act.

340. By virtue of these violations, Plaintiffs and the other members of the Class have

sustained damages.

341. Less than one year has elapsed from January 1, 2021 (the time that Plaintiffs could have discovered the facts for each element of the claims upon which the initial Section 11 complaint is based) to the time that the initial complaint was filed in this case. Less than three years elapsed between the time that the securities upon which this count is brought were offered and the time the initial Section 11 complaint was filed.

COUNT V

On Behalf of Plaintiffs and the Class Against Defendant Bristol for Violation of Section 12(a)(2) of the Securities Act

342. Plaintiffs incorporate each and every allegation set forth above as if fully set forth herein, except that for purposes of this claim, Plaintiffs expressly exclude and disclaim any allegation that could be construed as alleging or sounding in fraud or intentional or reckless misconduct. This claim is based solely on strict liability.

343. This count is brought pursuant to Section 12(a)(2) of the Securities Act, 15 U.S.C. §77l(a)(2), on behalf of the Class. This count is not alleging fraud or intentional conduct or recklessness.

344. Bristol is a "seller" for purposes 12(a)(2) of the Securities Act pursuant to 17 C.F.R. §230.159a.

345. Bristol had direct and active participation in the solicitation of Plaintiffs' and Class members' purchase and communicated directly with Plaintiffs and the Class through the offering materials for its own financial interest pursuant to the Registration Statement. Bristol, the issuer, is also a "statutory seller" under Section 12(a)(2).

346. Plaintiffs and the other members of the Class acquired CVR shares solicited and sold pursuant to the Registration Statement.

347. As alleged above, the Registration Statement contained untrue statements of material fact, omitted to state other facts necessary to make the statements made therein not misleading, and omitted to state material facts required to be stated therein.

348. Bristol owed to acquirers of their securities, including Plaintiffs and the other Class members, the duty to make a reasonable and diligent investigation of the statements contained in the Registration Statement to ensure that such statements were accurate and that they did not contain any misstatement or omission of material fact. Bristol, in the exercise of reasonable care, should have known that the Registration Statement and related documents contained misstatements and omissions of material fact. Bristol did not make a reasonable investigation or possess reasonable grounds for the belief that the statements contained in the Registration Statement were true and without omissions of any material facts necessary to make such statements not misleading.

349. Plaintiffs and the other members of the class acquired CVRs solicited by and pursuant to the Registration Statement and neither Plaintiffs nor the other Class members knew, or in the exercise of reasonable diligence could have known, of the untruths, inaccuracies and omissions contained in the Registration Statement.

350. By reasons of the conduct herein alleged, Bristol violated Section 12(a)(2) of the Securities Act.

351. By virtue of these violations, Plaintiffs and the other members of the Class have sustained damages. Accordingly, Plaintiffs and the other members of the Class who acquired CVRs pursuant to the Registration Statement have a right to rescind and receive their consideration paid, and hereby elect to rescind and tender their CVRs to Bristol. Members of the Class who have sold or had forfeited their CVRs are entitled to compensatory damages.

352. Less than one year has elapsed from the time that Plaintiffs discovered the facts

upon which the initial Section 12 complaint was based to the time that such complaint was filed. Less than three years elapsed between the time that the securities upon which this count is brought were offered to the public and the time the initial Section 12 complaint was filed.

COUNT VI

On Behalf of Plaintiffs and the Class Against Defendants Caforio, Sato, Arduini, Bertolini, Bancroft, Santiago, Emmens, Grobstein, Lacy, Paliwal, Samuels, Storch, and Vousden ("Section 15 Defendants"), for Violations of Section 15 of the Securities Act

353. Plaintiffs incorporate each and every allegation set forth above as if fully set forth herein, except that for purposes of this claim, Plaintiffs expressly exclude and disclaim any allegation that could be construed as alleging or sounding in fraud or intentional or reckless misconduct. This claim is based solely on strict liability.

354. This claim is brought pursuant to Section 15 of the Securities Act, 15 U.S.C. § 77o, on behalf of the Class, against the Section 15 Defendants.

355. The above allegations show a primary violation of the Securities Act.

356. The Section 15 Defendants were control persons of Bristol by virtue of, among other things, their positions as senior officers and directors of the Company. They were in positions to control, and did control, the false and misleading statements and omission contained in the Registration Statement.

357. The Section 15 Defendants at all relevant times participated in the operation and management of Bristol, and conducted and participated, directly and indirectly, in the conduct of Bristol's business affairs. The Section 15 Defendants were under a duty to disseminate accurate and truthful information with respect to Bristol's financial condition. Because of their positions of control and authority as officers and directors of Bristol, the Section 15 Defendants were able to, and did, control the contents of the Registration Statement, which contained materially false and

misleading statements

358. The Section 15 Defendants' control, ownership, and positions made them privy to and provided them with knowledge of the material facts concealed from Lead Plaintiffs and members of the Class.

359. None of the Section 15 Defendants made a reasonable investigation or possessed reasonable grounds for the belief that the statements contained in the Registration Statement were accurate and complete in all material respects. Had they exercised reasonable care, they could have known of the material misstatements and omission allege herein.

360. This claim was brought within one year after the discovery of the false and misleading statements and omissions in the Registration Statement and within three years after CVRs were distributed in connection with the Merger.

361. By reason of the misconduct allege herein, for which Bristol is primarily liable, as set forth above, the Section 15 Defendants are jointly and severally liable with and to the same extent as Bristol pursuant to Section 15 of the Securities Act. As a direct and proximate result of the conduct of the Section 15 Defendants, Plaintiffs and other members of the Class suffered damages in connection with their acquisition of CVRs pursuant to the Registration Statement.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment and relief as follows:

A. Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;

B. Awarding compensatory damages in favor of Plaintiffs and other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including pre- and post-judgment interest thereon;

C. Declaring that Defendants violated Sections 10(b), 14(a) and 20(a) of the

Exchange Act, as well as Rules 10b-5 and 14a-9 promulgated thereunder, and Sections 11, 12(a)(2), and 15 of the Securities Act and;

D. Awarding Plaintiffs' the costs of this action, including reasonable allowance for Plaintiffs' attorneys' and experts' fees; and

E. Granting such other and further relief as this Court may deem just and proper.

JURY DEMAND

Plaintiffs respectfully request a trial by jury on all issues so triable.

DATED: April 14, 2023

Respectfully Submitted,

By: /s/ Michael B. Eisenkraft

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Appendix A

CONFIDENTIAL WITNESSES

Confidential Witness #1 held an Executive Director position at Bristol from late 2019 until early 2021. Prior to that, Confidential Witness #1 was an Executive Director at Celgene from 2017 until late 2019. In these roles Confidential Witness #1 served as a patient safety lead for CAR-T drugs including liso-cel and was directly involved in the clinical trials and FDA approval for liso-cel. Prior to joining Celgene, Confidential Witness #1 had years of experience working on obtaining FDA approval for drugs, including an estimated twelve to thirteen drugs.

Confidential Witness #2 worked as a Manager at the Lonza facility in Texas from early 2018 until early 2020. In this role, Confidential Witness #2 was involved in compliance at the facility, including audits and inspections, and had direct interaction with Lonza's clients, including Juno Therapeutics and Bristol.

Confidential Witness #3 worked as a Senior Manager at the Lonza facility in Texas from mid-2020 until mid-2021 where Confidential Witness #3 oversaw logistics for the warehouse. Prior to joining Lonza, Confidential Witness #3 had extensive experience with both warehouse and logistics practices and FDA inspections. Confidential Witness #3 was hired by Lonza to help get its warehouse FDA-inspection ready, and during the inspection Confidential Witness #3 had direct contact with FDA inspectors. Confidential Witness #3 also had direct contact with Bristol employees during the preparation of the Lonza facility for the FDA audit.

Confidential Witness #4 worked as a Logistics Specialist at the Lonza facility in Texas from early 2019 until late 2020. During this time, Confidential Witness #5 worked in the Lonza warehouse, in particular, on supply chain management matters.

Confidential Witness #5 worked in the Goods Issuing department within the warehouse at the Lonza facility from late 2020 until early 2021. In this role, Confidential Witness

#5 handled internal and external requests to retrieve materials from the Lonza warehouse for shipment to external customers or for delivery to other departments at the Lonza facility. Confidential Witness #5 also had experience working in a pharmaceutical warehouse prior to joining Lonza.

Confidential Witness #6 worked as an Inventory Controller onsite at the Lonza Warehouse in Texas from late 2020 until mid-2021. Prior to joining Lonza, Confidential Witness #6 had experience with working in a warehouse for a chemical company.

Confidential Witness #7 worked as a Manager in the warehouse at the Lonza facility in Texas from late 2018 until late 2020. Prior to joining Lonza, Confidential Witness #7 worked for a medical technology company for almost eighteen years, through which Confidential Witness #7 experienced multiple FDA inspections of a facility.

Confidential Witness #8 worked as a viral vector manufacturing Technician at the Lonza facility in Texas from late 2019 until late 2020 during which time Confidential Witness #8 was involved in manufacturing the viral vector product for liso-cel. When working as a technician, Confidential Witness #8 had first-hand exposure to the production process of liso-cel.

Confidential Witness #9 is a former Bristol employee who contributed to updates to senior management in 2020.

Confidential Witness #10 was an executive in the quality department of BMS/Celgene during most of the relevant time period.

Confidential Witness #11 was a senior quality assurance specialist at Juno Therapeutics/Bristol Myers during the relevant time.